EPA Reg. Jacket 11556-155 vol 2

# PROCESSING REQUEST

Reg# 11554-15)	Decision #
Description:	
Electronic Label & Letter (see PPLS):	Non Electronic  R Label & Letter  (Scanning required):
X Dated:	□ Dated:
***Only one label ty	pe should be selected***
•	•
Other Materials Sent (see	jacket):
New CSF(s) Dated: .\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	17 AL+43
Other:	
and clipped together, NOT STAPLED. The materials to staff in the Information Servi	e, please file materials in a new jacket and
Reviewer: Autumn Metzger	
Division: RD – IVB 1	
Phone: 703-305-5314	Date:



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 7, 2017

Todd Frank Regulatory Affairs Consultant Bayer HealthCare P.O. Box 390 Shawnee Mission, KS 66201

Subject:

CSF Amendment - Adding Alternate CSF #3

Product Name: PNR1427 Insecticide EPA Registration Number: 11556-155 Application Date: August 18, 2017

Decision Number: 534540

Dear Mr. Frank:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/05/2017
- Alternate CSF 1 dated 06/06/2017
- Alternate CSF 2 dated 06/07/2017
- Alternate CSF 3 dated 11/16/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Autumn Metzger at 703-305-5314, or Metzger.autumn@epa.gov.

Sincerely,

Elizabeth Fertich

Product Manager 4

Invertebrate & Vertebrate Branch 1
Registration Division (7505P)

Office of Pesticide Programs



### ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

### DOCUMENT CONTAINS CONFIDENTIAL INFORMATION

DATE: November 6, 2017 **ACTION CODE: 345** DP BARCODE No.: 443811 File Symbol No.: 11556-155 DECISION No.: 534540

**COMPANY: BAYER HEALTHCARE LLC** PRODUCT NAME: "PNR1427 Insecticide"

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]

PC Codes: 036007; 129099

FROM: William Herald, Microbiologist (MS) / Chemist, REHS/Registered Sanitarian MARNET 7

Product Chemistry Team

Chemistry, Inerts and Toxicology Assessment Branch (CITAB) RD (7505P)

TO: Maggie Rudick / Kable B. Davis, PM 3

Invertebrate and Vertebrate Branch 1 / RD (7505P)

#### INTORDUCTION:

With a letter dated August 18, 2017Registrant, BAYER HEALTHCARE LLC has submitted an Alt. No. 2 CSF formulation (dated 8/16/17) to support the registration of the end use product, "PNR1427 Insecticide". Said proposed Alt. No. 2 CSF has replaced an ingredient. CITAB has been asked to evaluate the said proposed Alt No. 2 CSF formulation and determine its acceptability.

### SUMMARY OF FINDINGS:

- 1. The proposed Alt. No. 2 CSF formulation contains Flumethrin Technical (96.2%) [EPA Reg. No. 11556-154] as the active ingredients with the product label claims of 10.0% and 4.5% respectively.
- The nominal concentrations of the active ingredients concur with the product label claims of nominal concentrations in compliance with PR Notice 91-2 and Title 40 CFR § 152.43.
- 3. All of the inert ingredients present in the formulation have been approved by the Agency for non-food use only (V. Santa, 9/22/17).
- 4. The upper and lower limits of the active and inert ingredients are in compliance with the statutory parameters recited in Title 40 CFR § 158.350 (b) (2).
- The said proposed Alt No. 2 CSF formulation is substantially similar in chemical composition and physicalchemical properties with the current Basic CSF dated June 5, 2017.

#### CONCLUSION:

The CITAB has reviewed the said proposed Alt. No. SCSF formulation dated August 16, 2017 and has determined it to Chewy submitted one after was dated 1/11/17 daccepted by RD sine changes insignificantly different to this memo, be acceptable.

## Metzger, Autumn

From:

Todd Frank <todd.frank@bayer.com>

Sent:

Thursday, November 16, 2017 1:59 PM

To:

Metzger, Autumn

Subject:

RE: Seresto Collar - Bayer Animal Health 11556-155

#### THANK YOU VERY MUCH!!!

Have a great day and Holiday!

Todd

From: Metzger, Autumn [mailto:Metzger.Autumn@epa.gov]

Sent: Thursday, November 16, 2017 12:47 PM

To: Todd Frank

Cc: IVB1

Subject: RE: Seresto Collar - Bayer Animal Health 11556-155

Ok, I talked to PC and I went ahead and switched out the one you sent for the one that was accepted. So I have sent Beth (the PM) the amendment letter to sign. She's got a huge stack though so it may be a week or so since we have a holiday coming up before it gets signed, either way we're way ahead of the original schedule, which we thought was getting pushed back due to the change, but it didn't.

Thanks for the prompt responses and help!

Autumn Metzger Invertebrate & Vertebrate Branch 1 Registration Division Office of Pesticides 703-305-5314

From: Todd Frank [mailto:todd.frank@bayer.com]
Sent: Thursday, November 16, 2017 11:09 AM
To: Metzger, Autumn < Metzger.Autumn@epa.gov>

Subject: RE: Seresto Collar - Bayer Animal Health 11556-155

Hi Autumn.

Attached is the update CSF as discussed.

We updated the name to include Alternate 3 and used today's date.

Let me know if you have any questions.

Thank you, Todd

Todd Frank Regulatory Affairs Consultant Bayer U.S. Animal Health Research & Development P.O. Box 390 Shawner (2012) 200 2005

Phone: (913) 268-2585 E-mail: todd.frank@bayer.com

**From:** Metzger, Autumn [mailto:Metzger.Autumn@epa.gov]

Sent: Thursday, November 16, 2017 8:36 AM

To: Todd Frank

Subject: RE: Seresto Collar - Bayer Animal Health 11556-155

Hi Todd,

Can you call when later this morning when you have a chance? Since I got this package late, then a new CSF later I want to verify what we have and reviewed was the correct one before we finish it up.

Thanks!

Autumn Metzger Invertebrate & Vertebrate Branch 1 Registration Division Office of Pesticides 703-305-5314

From: Todd Frank [mailto:todd.frank@bayer.com]

Sent: Thursday, October 26, 2017 3:14 PM

**To:** Metzger, Autumn < <u>Metzger.Autumn@epa.gov</u>> **Subject:** RE: Seresto Collar - Bayer Animal Health

Hi Autumn,

Very good news. Thank you for the update.

Again if any questions please let us know!

Have a wonderful day!

Todd

From: Metzger, Autumn [mailto:Metzger.Autumn@epa.gov]

Sent: Thursday, October 26, 2017 2:04 PM

To: Todd Frank

Subject: FW: Seresto Collar - Bayer Animal Health

Hi Todd,

I have set up to talk to the Product Chem team on Tuesday about this one. I think the switch is do-able but may just push the review back a little. I'll confirm with you on Tuesday.

Autumn Metzger Invertebrate & Vertebrate Branch 1 Registration Division

## Office of Pesticides 703-305-5314

From: Fertich, Elizabeth

**Sent:** Thursday, October 19, 2017 3:21 PM **To:** Todd Frank < todd.frank@bayer.com>

Cc: Davis, Kable < Davis.Kable@epa.gov >; Rudick, Maggie < Rudick.Maggie@epa.gov >; Metzger, Autumn

<Metzger.Autumn@epa.gov>

Subject: RE: Seresto Collar - Bayer Animal Health

Hi Todd,

Maggie is out the office for a few weeks, so I'm transferring this to Autumn Metzger. She'll let you know about swapping out the CSF.

Kind regards,

Beth

From: Fertich, Elizabeth

**Sent:** Wednesday, October 18, 2017 4:25 PM **To:** 'Todd Frank' <todd.frank@bayer.com>

Cc: Davis, Kable < <u>Davis.Kable@epa.gov</u>>; Rudick, Maggie < <u>rudick.maggie@epa.gov</u>>

Subject: RE: Seresto Collar - Bayer Animal Health

Hi Todd,

Maggie Rudick has been working on this action and sent the CSF to the chemistry team for review. I will see how far along they are and whether it's possible to swap out the CSFs at this time. I'll get back to you soon. Kind regards,

Beth

From: Todd Frank [mailto:todd.frank@bayer.com]
Sent: Wednesday, October 18, 2017 2:52 PM
To: Davis, Kable < Davis.Kable@epa.gov>

**Cc:** Fertich, Elizabeth < <a href="mailto:fertich.elizabeth@epa.gov">fertich.elizabeth@epa.gov</a> <a href="mailto:Subject: RE: Seresto Collar - Bayer Animal Health">Subject: RE: Seresto Collar - Bayer Animal Health</a>

Hi Bo,

We submitted the MFA for the Collars to add a new alternate inert back in August and we wanted to see if it would be ok to replace that CSF with a new one? The new CSF has the same date as the original CSF. The only change was the addition of a second supplier for the new inert.

Attached is the new CSF with the alternate ingredient and the supplier composition statement.

If you have any question please let us know.

Todd

Todd Frank Regulatory Affairs Consultant Bayer U.S. Animal Health Research & Development P.O. Box 390 Shawnee Mission, KS 66201-0390 Phone: (913) 268-2585 E-mail: todd.frank@bayer.com

From: Davis, Kable [mailto:Davis.Kable@epa.gov]

Sent: Monday, August 21, 2017 7:22 AM

To: Todd Frank Cc: Fertich, Elizabeth

Subject: FW: Seresto Collar - Bayer Animal Health

Hi Todd -

Thanks for the heads up. We will keep a lookout for the submission.

Enjoy the day.

Во

Kable Bo Davis Acting Branch Chief Invertebrate & Vertebrate Branch 1 (703) 306-0415 davis.kable@epa.gov

From: Todd Frank [mailto:todd.frank@bayer.com]

Sent: Monday, August 21, 2017 8:18 AM To: Davis, Kable < Davis.Kable@epa.gov> Subject: Seresto Collar - Bayer Animal Health

Hi Bo,

We just wanted to send you a copy of the minor formulation amendment we just submitted to your attention.

Please let me know if you need any additional information in support of the application.

Have a great day! Todd

Todd Frank

Regulatory Affairs Consultant

Bayer U.S. Animal Health Research & Development P.O. Box 390 Shawnee Mission, KS 66201-0390 Phone: (913) 268-2585

E-mail: todd.frank@bayer.com



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 25, 2017

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DR. ROBERT ZOLYNAS BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION PO Box 390 SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: PNR1427 INSECTICIDE

COMPANY NAME: BAYER HEALTHCARE LLC

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 11556-155 EPA RECEIPT DATE: 08/21/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at {Phone Number}.

Sincerely,

Front and Processing Staff Information Services Branch

Information Technology & Resources Management Division

## FAST-TRACK AMENDMENTS – Completeness Screening Checklist

PA I	Reg. Number: 11556-155 EPA Receipt Date: 8/18	117		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	D		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	Ø		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed? - a) Selective Method? - b) Cite-All Method? - c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)			
	a) Electronic Label submitted?			
	Comments:  There Review  Inerts approved for use as intention  U	ded Saw	9/5	2/20/

e/Edit Collections Utilities Query Tool	Po Help	Exit			
S: 1008078 Milestone egulatory Type: Product Registration - Section	-	Resubmission:	_	= -	Print Letter
oplication Type: Amendment	~	Fee For Service: Billable:	Yes Yes	_	Enter More Information Tracking
Company: 11556 BAYER HEALTHCA	RE LLC	V			
Risk Manager: Registration Division, Risk Ma	nagement Team 3		~		
Product #: 11556-155 Product Nar	me: PNR1427 INSECTICIDE				
Qverride#:					
Me Too Me Too F Section3: Nam	A. C.				
Application Date: 18-Aug-2017	OPP Rec'vd Date:	21-Aug-2017	<b>6</b>	Receipt	Content
Front End Date: 25-Aug-2017	Risk Manager Send Date:	25-Aug-2017	63	CSF	
FFS Due Date:	Negotiated Due Date:				
OPP Target Date:		•		<	
Fast Track: New in Receipt Description:	ngredient:				View/Edit
AMENDMENT			New Ingre		
			New Ingra Received		
Form A. Signature Date:		Form 8:	Signatura	Date	



# Fee for Service {1008078`~

This package includes the following	for Division
New Registration  Amendment	○ AD ○ BPPD • RD
Studies? Fee Waiver?  volpay % Reduction:	Risk Mgr. 3
Receipt No. S-	1008078
EPA File Symbol/Reg. No.	11556-155
Pin-Punch Date:	8/21/2017
This item is NOT subject to	FFS action.
Action Code:	Parent/Child Decisions:
Requested:	
Granted:	
Amount Due: \$	(Same)
⊠ Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer: Shanta Adelb	Santa 9/22/2017 Date: 8/25/17
Remarks: Inext Screen need	ed

## Bayer HealthCare



Bayer HealthCare LLC

Animal Health

P.O. Box 390 Shawnee Mission, KS

66201-0390

Document Processing Desk (7504P) - (AMEND) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn: Kable B. Davis, IVB1

August 18, 2017

Subject:

Amendment to add alternate inert

PNR1427 Insecticide EPA Reg. No. 11556-155

Dear Mr. Davis.

Bayer HealthCare LLC Animal Health is submitting an Amendment for the subject product to add an alternate formulation. The new inert is

In support of this application, we are submitting the following documentation:

- 1. EPA Form 8570-1 dated 08/18/2017
- 2. 2 copies each of EPA Form 8570-4 -- Confidential Statement of Formula (CSF) for the Alternate CSF dated 08/16/2017.
- 3.
- 4.
- 5.
- Email from Kerry Leifer dated 06/28/2017

Should you have any questions regarding this submission, please call me at (913) 268-2585 or email todd.frank@bayer.com.

Regards,

Took Fred

Regulatory Affairs Consultant

\*Manufacturing process information may be entitled to confidential treatment\*

	· · · · · · · · · · · · · · · · · · ·		Form App	roved. OMP	lo. 2070-00	60 Franceouth
<b>\$EPA</b>	United States Environmental Protecti Washington, DC 20			R.	stration ndment	OPP Identifier Number
	Applicati	on for Pesti	cide - Sec	tion I		
1. Company/Product Number 11556-155	of		<b>A Product Mar</b> e B. Davis	ager	3.	Proposed Classification
4. Company/Product (Name PNR 1427 Insecticide	)	PM# Tea	m Number 3			X None Restricted
5. Name and Address of Ap Bayer HealthCare LLC, A P.O. Box 390 Shawnee Mission, KS 6	Animal Health Division	(b)(i), to: EPA				ith FIFRA Section 3(c)(3) composition and labeling
		Section				
X Notification - Explain	ponse to Agency letter dated below. nal page(s) if necessary. (For section	on I and Section II	Agency let "Me Too" Other - Exp	d labels in respected dated Application. Italian below.	ponee to	
E-mail Contact: todd.fra  1. Material This Product Wi		Section -	- III			
Child-Resistant Packaging Yes* No * Cartification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Yes No If "Yes" Package wgt	No. per contains		Metal Plasti Glass Papel Other	l ic
3. Location of Net Contents	Information 4, Size(s) Re Container	tail Container			Label	otions ompanying product
6. Manner in Which Label is	Affixed to Product Lithor	graph glued siled	Othe			
		Section -	IV			
1. Contact Point  Complete	items directly below for identification	on of individual to	be contacted,	if necessary,	to process t	his application.)
Name J. Todd Frank		Title Reg. Affairs Co	nsultant			one No. (Niclude Area Code) 68-2585
the second secon	Certification of the comments I have made on this form and any knowingly false or misleading states.	d all attachments tement may be pu				e. Detr Application Received (Stamped)
2. Signature		3. Title				

Regulatory Affairs Consultant

5. Date

Aug 18, 2017

4. Typed Name

J. Todd Frank

-g0 <u>-</u> 0	ert & product ingrediei	cca.co informa	 u voimuoni	a caumo

Todd Frank		
Subject:	FW: Non-food Use of	- Request for Information

## Begin forwarded message:

From: "Leifer, Kerry" < Leifer.Kerry@epa.gov>

Date: June 28, 2017 at 3:13:11 PM CDT

To: "doug.spilker@bayer.com" <doug.spilker@bayer.com>

Cc: "Shah, Pv" <Shah.Pv@epa.gov>

Subject: RE: Non-food Use of Request for Information

Doug,

Regarding your inquiry, we have added to our internal database as an approved nonfood use inert ingredient and will also be adding it to InertFinder. A food use approval would require the submission of a tolerance exemption petition and an accompanying PRIA fee (likely under PRIA category 1003).

Regarding we will need to have the full composition of that product provided to us so that we can verify its acceptability for use as an inert ingredient. Please see FAQ #12 at <a href="https://www.epa.gov/sites/production/files/2015-12/documents/faqs.pdf">https://www.epa.gov/sites/production/files/2015-12/documents/faqs.pdf</a>

Finally, regarding the submission of an alternate formulation, that would be evaluated on an individual case basis.

Please feel free to contact me directly if you have any further questions.

Sincerely,

Kerry

Kerry Leifer, Team Leader
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
tel: (703) 308-8811

tel: (703) 308-8811 fax: (703) 605-0781

e-mail: leifer.kerry@epa.gov

From: Shah, Pv

Sent: Tuesday, June 27, 2017 4:18 PM
To: Leifer, Kerry < Leifer. Kerry@epa.gov >

Subject: Fwd: Non-food Use of Request for Information

## Sent from my iPhone

## Begin forwarded message:

From: Doug Spilker < doug.spilker@bayer.com>

Date: June 22, 2017 at 1:54:29 PM EDT

To: "shah.pv@epa.gov" <shah.pv@epa.gov>, "inertsbranch@epa.gov"

<inertsbranch@epa.gov>

Cc: Brad McKinnis <brad.mckinnis@bayer.com>, Todd Frank

<todd.frank@bayer.com>

Subject: Non-food Use of \_\_\_\_\_\_ - Request for

Information

Dear PV,

In looking through the Inert-Finder data base, we noticed that:

6.0			



We would like to include the ingredient for the use product at the same level.

Since both of the	are approved, how would we get approval
for the	for non-food use products?

Thank you and,

Best regards,

Doug

Douglas A. Spilker, Ph.D. Manager, EPA Regulatory Affairs

Bayer: Science For A Better Life

Bayer U.S. LLC Animal Health R&D, Regulatory Affairs P.O. Box 390 Shawnee, KS 66201 USA

Tel: +1 913 268 2751 Mobile: +1 816 506 3102

E-mail: <a href="mailto:doug.spilker@bayer.com">doug.spilker@bayer.com</a>
Web: <a href="mailto:http://www.bayer.com">http://www.bayer.com</a>

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# PROCESSING REQUEST

Description: Update Basic +# +2 CSF	
Electronic Label & Letter On Non Electronic	
(see PPLS): OR Label & Letter	
(Scanning required):	
☐ Dated: ☐ Dated:	
***Only one label type should be selected***	
Only one most type should be selected	
Other Materials Sent (see jacket):	
New CSF(s) Dated: 6-5; 6-6; 6-7-17	
Other:	
,	
File this coversheet and attached materials in the jacket. It must be well organd clipped together, NOT STAPLED. Then give the jacket with the coversheem aterials to staff in the Information Services Center (ISC) (Room S-4900). I jacket is full or only available as an image, please file materials in a new jack bring it down to the (ISC). For further information please call 703-605-0716	et and f a et and
Reviewer: Angela Hollis	
Reviewer: Angela Hollis  Division: RD	



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 20, 2017

J. Todd Frank Regulatory Affairs Consultant Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201

Subject: CSF Notification per PRN 98-10 – Updating Basic CSF, Alternate CSFs 1 and 2

Product Name: PNR1427 INSECTICIDE EPA Registration Number: 11556-155

Application Date: 06/09/2017 Decision Number: 530453

Dear Mr. Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/05/2017
- Alternate CSF 1 dated 06/06/2017
- Alternate CSF 2 dated 06/07/2017

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Angela Hollis at 703-347-0216 or by email at hollis.angela@epa.gov.

Sincerely,

Elizabeth Fertich

Acting Product Manager 03

Invertebrate & Vertebrate Branch 1 Registration Division (7505P)

Office of Pesticide Programs

Please read instructions on reverse b	efore corr ting form.	Form Approv	Ve 2MB No. 2070-0060	Print Form
SEPA Envir	United States  Onmental Protection  Washington, DC 20460	-	Registration Amendment  Other	OPP Identifier Number
	Application	for Pesticide - Secti	on I	· · · · · · · · · · · · · · · · · · ·
1. Company/Product Number 11556-155		2. EPA Product Manag Kable B. Davis	jer 3. Pro	oposed Classification
4. Company/Product (Name) PNR 1427 Insecticide		PM# Team Number 3	×	None Restricted
5. Name and Address of Applicant (In Bayer HealthCare LLC, Animal He P.O. Box 390 Shawnee Mission, KS 66201-039 Check if this is a new	ealth Division  0  address	(b)(i), my product is to:	ew. In accordance with similar or identical in con	mposition and labeling
		Section - II		
Amendment - Explain below.  Resubmission in response to A  X Notification - Explain below.	gency letter dated	Final printed I Agency letter "Me Too" Ap Other - Explain	plication.	
Minor Revisions to Address of Ine E-mail Contact: todd.frank@baye			JUL 2 I	0 2017
		Section - III		
1. Material This Product Will Be Pack	aged In:			
Yes* No If "Yes"	o No. per	Yes No Tes No. per Package wgt container	2. Type of Container  Metal Plastic Glass Paper Other (S	Specify)
3. Location of Net Contents Informati	on 4. Size(s) Retail (	Container 5	. Location of Label Directio On Label On Labeling accom	
6. Manner in Which Label is Affixed t	Paper glue Stenciled	sd		
		Section - IV		
1. Contact Point   Complete items dir	actly below for identification of	findividual to be contacted, if	necessary, to process this	application.)
Name J. Todd Frank	Titl Re	g. Affairs Consultant	<b>Telephone</b> 913-268-	e No. (Include Area Code) -2585
I certify that the statements I h I acknowledge that any knowin both under applicable law.		attachments thereto are true,		8. Date Applicatio Recoived (Stamped)
2. Signature	3. T	îtle		
8. Too Rue	Reg	gulatory Affairs Consultant		
4. Typad Name	5. D	ate		
J. Todd Frank	Ju	n 9, 2017		

## Bayer HealthCare



Document Processing Desk (7504P) – (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Kable B. Davis, IVB1 Chief (acting)

June 9, 2017

Subject:

Notification to update supplier names

PNR1427 Insecticide EPA Reg. No. 11556-155

Dear Mr. Davis,

Bayer HealthCare LLC Animal Health is submitting a Notification for the subject product to revise supplier names for some inerts ingredients and add alternate suppliers for some of the non-proprietary inert ingredients.

In support of this application, we are submitting the following documentation:

- EPA Form 8570-1, with Confidential Explanation Page
- 2 copies each of EPA Form 8570-4 -- Confidential Statement of Formula (CSFs) for the Basic and two Alternate CSF's dated 06/5/2017, 06/06/2017, and 06/07/2017.
- 1 copy of the most recent approved Basic and Alternate CSF's dated 08/25/2010.

Should you have any questions regarding this submission, please call me at (913) 268-2585 or email todd.frank@bayer.com.

Regards,

J. Todd Frank

Regulatory Affairs Consultant

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Bayer HealthCare LLC

Animal Health

P.O. Box 390 Shawnee Mission, KS 66201-0390



Bayer Animal Health

P.O. Box 390

Development, North America

Shawnee, KS 66201-0390

Document Processing Desk (**7504P**)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

September 15, 2016

Attention: Kable B. Davis, Team 3

Subject:

PNR1427 Insecticide (EPA Reg. No. 11556-155)

Withdrawal of Amendment to revise directions for use to add Medium

Dog

Dear Mr. Davis,

Bayer HealthCare LLC Animal Health is requesting withdrawal without prejudice of our July 22, 2016 Amendment for the subject product.

After further review of the current market, Bayer does not wish to pursue the development of the additional product at this time.

Should you have any questions regarding this submission, please call me at (913) 268-2585 or email todd.frank@bayer.com.

Regards,

J. Todd Frank

Regulatory Affairs Consultant

cc: D. A. Spilker

## Bayer HealthCare



Document Processing Desk (**7504P**) – (**NON-PRIA AMEND**)
Office of Pesticide Programs (**7504P**)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

July 22, 2016

Attention: Kable B. Davis, Team 3

Subject:

PNR1427 Insecticide (EPA Reg. No. 11556-155)

Amendment to revised directions for use to add Medium Dog

Dear Mr. Davis,

Bayer HealthCare LLC Animal Health is submitting an Amendment for the subject product to add an Alternate Brand Name (ABN) and minor revisions to the directions for use to add Medium size dog directions. The Medium dog collar is identical to the Large dog collar in composition and claims.

Bayer HealthCare LLC

Animal Health

P.O. Box 390 Shawnee Mission, KS 66201-0390

In support of this application, we are submitting the following documentation:

- Application Form 8570-1, dated 7/22/2016
- 2. PNR1427 Insecticide labeling (version g) 3 copies
- PNR1427 Insecticide labeling (version g highlighted) 3 copies
- 4. CD containing PDF versions of the labels

Should you have any questions regarding this submission, please call me at (913) 268-2585 or email todd.frank@bayer.com.

Regards,

J. Todd Frank

1, Took Fulk

Regulatory Affairs Consultant

cc: D. A. Spilker



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 27, 2016

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DR. BRUCE MARTIN
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: PNR1427 INSECTICIDE

COMPANY NAME: BAYER HEALTHCARE LLC

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 11556-155 EPA RECEIPT DATE: 07/26/16

SUBJECT: RECEIPT OF AMENDMENT

**DEAR REGISTRANT:** 

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 3, at (703) 306-0415.

Sincerely

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

Please read instructions on reverse before comp' 'ng form.	Form Ap	proved. MB No. 2070-	OOGO Print Form
SEPA Environmental Protection Washington, DC 20		× negistratio Amendmen Other	OPP Identifier Number
Applicati	ion for Pesticide - Se	ction I	
1. Company/Product Number 11556-155	2. EPA Product Ma Kable B. Davis	nager	3. Proposed Classification
<b>4. Company/Product (Name)</b> PNR1427 Insecticide	PM# Team Number 3		X None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Bayer HealthCare LLC, Animal Health Division P.O. Box 390  Shawnee Mission, KS 66201-0390  Check if this is a new address		t is similar or identical	with FIFRA Section 3(c)(3) in composition and labeling
	Section - II		
Amendment - Explain below.      Resubmission in response to Agency letter dated      Notification - Explain below.  Explanation: Use additional page(s) if necessary. (For section NON-PRIA Amendment to add ABN and revised direction.)	Other - Ex	ed lebels in response to otter deted Application.  cplain below.	
E-mail Contact: todd.frank@bayer.com			
	Section - III		
Material This Product Will Be Packaged In:			
Child-Resistant Packaging  Yes*  X No  * Certification must be submitted  Unit Packaging  Yes  X No  If "Yes" Unit Packaging wgt.  No. per Unit Packaging wgt.	Water Soluble Packaging Yes X No If "Yes" No. per Package wgt contain	Pi Gi	tainer etal estic ess eper ther (Specify)
	etail Container	5. Location of Label D  X On Label X On Labeling	irections accompanying product
6. Manner in Which Label is Affixed to Product  Litho Pape Sten	ograph Oth or glued ciled	er	
	Section - IV		
1. Contact Point (Complete items directly below for identificat	ion of individual to be contacted		
Name J. Todd Frank	Title Reg. Affairs Consultant		aphone No. (Include Area Code) 3-268-2585
Certific I certify that the statements I have made on this form an I acknowledge that any knowlegly false or misleading sta both under applicable law.	d all attachments thereto are tr		9. Dare Application Received (Stamped)
2. Signature  P. Town Green	3. Title Regulatory Affairs Consult	ent	
4. Typod Name J. Todd Frank	5- Oate 07/22/2016		



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 3, 2014

Mr. J. Todd Frank
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject:

Amendment: Revised Marketing Claims

PNR 1427 Insecticide EPA Reg. No. 11556-155

Your Submission Dated February 20, 2014

Dear Mr. Frank:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander at Alexander, bewanda@epa.gov or (703) 305-7460.

Sincerely,

Richard Gebken

Product Manager Team 10

Insecticide Branch

Registration Division (7505P)

Enclosure

alexander for

Reason To Issue: Minor revisions to claims. Date: 02/17/14
Supersedes: 05/29/13
Page 1 of 14

Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

## PNR1427 Insecticide

Alternate Brand Names: Seresto Small Dog; Seresto Large Dog; Seresto Cat

## Optional Language for Small Collar

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]]
-or-

[For 8-month prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older]

-or-

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]] [and/or] prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older]

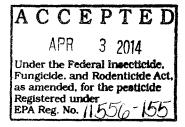
## Optional Language for Large Collar:

[For 8-month prevention and treatment of ticks, fleas and lice for 8 months on (large) dogs and puppies 7 weeks of age and older and above [(18 lbs.)(8 kg)] [body weight] ]

• [Selected optional label claims bulleted here from pages 9 to 15]	
ACTIVE INGREDIENTS:	
Flumethrin *	4.5%
Imidacloprid	10.0%
OTHER INGREDIENTS	85.5%
Total	100%
*Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2	
Net Contents: (X) Collar (s) – XX oz. (XX grams)	

PNR 1427 Insecticide 052913f.doc

EPA Reg. No. 11556-155



**EPA Est. No. 11556-TBD** 

Date: 02/17/14

Supersedes: 05/29/13

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## Manufactured For

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA

Made in Germany

## READ THE ENTIRE LABEL BEFORE USE

[For small collar: USE ON [(DOGS)(CATS)]]

-or-

[For small collar: USE ON SMALL DOGS and CATS]

-or-

[For large collar: USE ONLY ON DOGS]

## DO NOT OPEN UNTIL READY TO USE DO NOT LET CHILDREN PLAY WITH THIS COLLAR [OR REFLECTORS]

## KEEP OUT OF REACH OF CHILDREN [CHOKING HAZARD - CONTAINS SMALL PARTS]

See [(back panel)(insert)] for Directions for Use.

## HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS or ANIMALS, call 1-800-422-9874.

Date: 02/17/14

Supersedes: 05/29/13 Page 3 of 14

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

## HOW TO APPLY

One collar per animal to be fastened around the neck.

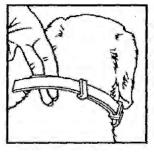
Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar. Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight or leaving it too loose. As a guide, it should be possible to only insert 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Collar length of greater than (1/one/an) inch (2 cm) beyond the loop(s) should be cut off unless it is on a growing [(puppy)(kitten)], where some additional length may be needed for adjustment as the animal grows.

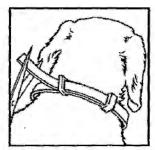
[After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.]

### Optional Visuals:

#### Dog



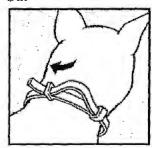


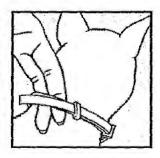


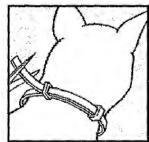


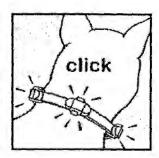
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#### Cat









The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when [(puppies)(kittens)] are rapidly growing.

This collar is designed with a release[(system)(mechanism)]. In the unlikely event of a [(dog)(cat)(pet)] being trapped, the [(dog's)(cat's)(pet's)] own strength is sufficient to widen the collar to allow for quick release.

Replace the collar after 8 months for (optimal) (continuous) flea and tick protection.

### PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

[(PNR 1427 Insecticide)(Brandname)(This product)(The collar)] kills existing fleas on [(dogs)(cats)] within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in control of flea larvae in the [(dog's)(cat's)] surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) treated [(dog)(cat)].

Ticks already on the [(dog)(cat)] prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the [(dog)(cat)]. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

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Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours.

(Kills lice on dogs.)

Aids in the treatment (and control) of Sarcoptic mange on dogs.

[(Seresto) (PNR 1427 Insecticide) (This product)(The collar)] is [(water resistant) (waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for flea control and reduced to 7 months for tick control.

Occasionally scratching may be observed in animals that are not used to wearing collars during the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. For further guidance regarding individual animal sensitivities, see information below.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar (or reflectors,) or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. [Choking hazard. Contains small parts]. Do not place collar [or reflectors] in mouth. Not intended for use on humans.

For external use on [(dogs)(and)(cats)] only. Do not use on other animals. [(Do not use on puppies under seven weeks of age.)(Do not use on kittens under ten (10) weeks of age.)] Do not get this product in [(dog's)(cat's)] eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or musing animals. Individual sensitivities, while rare, may occur after using ANY pessicide product for pets. Rarely, mild application site reactions may occur, such as scratching, redness and hair loss, which usually recover within 1 to 2 weeks without the need for collar removal. In some cases, a temporary collar removal and bathing may be recommended until symptoms have disappeared. In very rare cases, application site reactions such as dermatitis, inflammation, eczema or lesions may occur. In these instances, collar removal is

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recommended. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your [(dog)(or)(cat)] is experiencing an adverse event, contact your veterinarian and, call 1-800-422-9874.

The patented [(sustained)(slow)(steady)(continuous)][(release)(distribution)] technology ensures that both active [(substances) (ingredients)] are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active [(substances)(ingredients)] are present in the [(cat's)(and/or)(dog's)] haircoat during the entire [(protection)(efficacy)] period. The active [(substances)(ingredients)] spread from the site of direct contact over the skin surface.

## [INSERT DIAGRAM THAT DEPICTS RELEASE FROM MATRIX.]

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Do not use container for food storage or other purposes.

**Pesticide Storage**: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of pouch and expired collar in trash. Outer container may be recycled or disposed of in trash.

## LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc. [The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.]

Date: 02/17/14

Supersedes: 05/29/13

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### Pouch Label

[(PNR 1427 Insecticide)(Brand name)]

4.5% flumethrin 10.0% imidacloprid

Do not let children play with this collar (or reflectors). FOR USE ON (CATS)(DOGS)(CATS & DOGS) See (outer container/leaflet/insert) for complete label information. Do not open until ready to use.

BAYER HealthCare LLC, Animal Health Division

EPA Reg. No. 11556-155 EPA Est. No. 11556-TBD

Lot No. 0000000

## Calendar Reminder Sticker

Use[(this)(attached)(included)] calendar sticker to remind you when your [(dog)(cat)(pet)] is due for its next application.

> [(PNR 1427 Insecticide)(Brand name)] Make sure to replace collar after 8 months

Mobius Loop on outer container

Fe

Package

Date: 02/17/14

Supersedes: 05/29/13

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Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

## **Optional/Alternative Marketing Claims – Dogs**

### General Claims - Dogs

- Two active [(substances)(ingredients)] provide dual action against ticks, fleas, and lice (on dogs)
- For use on dogs and puppies 7 weeks of age and older
- Tick, (and) flea (and lice) (prevention)(control)(and) treatment for dogs 7 weeks of age or older
- [(PNR 1427)(Brand name)(This product)] is indicated for the prevention and treatment of ticks, fleas and lice on dogs and puppies (7 weeks of age and older)
- [Effective][Long-lasting] [protection] against ticks and fleas for 8 months
- [Effective][Long-lasting] [protection] against ticks, fleas and lice for 8 months
- Kills (and repels) ticks, (and) kills fleas (for 8 months)
- Reliable 8-month protection against ticks, and fleas on dogs (and puppies)
- Reliable 8-month protection against ticks, fleas and lice on dogs (and puppies)
- [3-way] protection against fleas, ticks and lice
- 8-month protection against ticks and fleas
- 8-month protection against ticks, fleas and lice
- For (small) dogs up to [(18 lbs.)(8 kg)] [body weight]
- For (large) dogs above [(18 lbs.)(8 kg)] [body weight]
- For external use on dogs
- For [(small dogs and puppies)(large dogs)]
- Fully effective within 48 hours after initial application of collar

#### Tick Claims - Dogs

- Repels and kills ticks for 8 months, including [(Deer)(Black-legged)] ticks, (Ixodes scapularis) (vector of Lyme disease and anaplasmosis), American dog ticks, (Dermacentor variabilis) (vector of Rocky Mountain spotted fever and ehrlichiosis), Brown dog ticks, (Rhipicephalus sanguineus) (vector of ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis, and Rocky Mountain spotted fever). and Lone Star ticks (Amblyomma americanum) (vector of ehrlichiosis)
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (Anaplasma phagocytophilium), Bartonellosis (Bartonella vir.sonii, Bartonella spp.), Babesiosis (Babesia canis, B. gibsoni), Borreliosis (Borrelia burgdorferi), canine hemoplasmosis (Mycoplasma haemocanis), Ehrlichiosis (Ehrlichia canis, E. chaffeensis, E. ewingii), Hepatozoonosis (Hepatozoon canis and H.

Page 9 of 14

americanum), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (canine) vector borne diseases]

- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (Anaplasma phagocytophilium), Bartonellosis (Bartonella vinsonii, Bartonella spp.), Babesiosis (Babesia canis, B. gibsoni), Borreliosis (Borrelia burgdorferi), canine hemoplasmosis (Mycoplasma haemocanis), Ehrlichiosis (Ehrlichia canis, E. chaffeensis, and E. ewingii), Hepatozoonosis (Hepatozoon canis and H. americanum), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (canine) vector borne diseases]
- Kills [(Deer)(Black-legged)] ticks (, which may carry Lyme disease and Anaplasmosis)
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever and Ehrlichiosis)
- Kills all [(life)(blood feeding)] stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (initial) application
- Prevents tick infestations within 48 hours after (initial) application
- [(Kills)(Repels)] ticks in 6 hours after (initial) efficacy has been obtained
- Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours
- Protects against all types of ticks (attacking dogs)
- Protects your (dog)(and/or)(puppy) from all types of ticks (for 8 months)
- Easy, effective [(treatment and prevention)(control)] of ticks, (and) fleas (,and lice)

### Flea Claims - Dogs

- (Rapidly/Quickly]) Kills fleas on dogs within [24] hours and continues to prevent infestations for 8 months
- Kills and repels fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months
- Seresto aids in control of flea larvae in the dog's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide)]-treated dog.
- Aids in the control of flea larvae in the dog's immediate surroundings
- Protects your (dog)(and/or)(puppy) from fleas (for 8 months)
- For the treatment and prevention of flea infestations [on your dog (and in your dog's immediate surroundings)]
- One treatment prevents further flea infestations (on dogs) for 8 months
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents fleas on treated dogs from infesting (reinfesting) your home

Reason To Issue: Minor revisions to claims. Date: 02/17/14

Supersedes: 05/29/13

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• Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]

- For prevention and treatment of flea infestation(s) for 8 months
- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on dogs
- Kills cat fleas (Ctenocephalides felis,) dog fleas (Ctenocephalides canis) and human fleas (Pulex irritans) on dogs
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas that may vector tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii*, *Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Efficacy against fleas that may vector tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii, Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in dogs

#### Flea & Tick Claims - Dogs

- REPELS AND kills fleas and ticks and kills lice on dogs and puppies 7 weeks of age and older and above 18 lbs. (8kg)
- REPELS AND kills fleas and ticks and kills lice on dogs and puppies 7 weeks of age and older and up to 18 lbs. (8kg)
- REPELS AND kills fleas and ticks and kills lice on dogs
- REPELS AND kills fleas and ticks

#### Lice & Other Efficacy Claims - Dogs

- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice (infestations)
- Controls existing [(biting) (chewing)] lice infestations
- Treats, prevents and controls [(biting) (chewing)] lice (infestations)
- Provides effective control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations of [(biting) (chewing)] lice
- Aids in the treatment (and control) of Sarcoptic mange on dogs

### **Optional/Alternative Marketing Claims – Cats**

Date: 02/17/14 Supersedes: 05/29/13

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#### **General Claims - Cats**

- Two active [(substances)(ingredients)] provide dual action against ticks and fleas (on cats)
- For use on cats and kittens 10 weeks of age and older
- [Effective][Long-lasting] [ protection] for 8 months
- Tick, (and) flea (prevention)(control)(and) treatment for kittens 10 weeks of age or older
- Tick and flea treatment for cats and kittens 10 weeks of age and older
- [(PNR 1427)(Brand name) (The collar)(This product)] is indicated for the prevention and treatment of ticks and fleas on cats and kittens (10 weeks of age and older)
- Kills (and repels) ticks and kills fleas (for 8 months)
- (Reliable) (8-month) protection against ticks and fleas [on cats (and kittens)]
- [Dual] [2-way] protection against ticks and fleas
- For external use on cats
- For cats and kittens
- Fully effective within 48 hours after initial application of collar

#### Tick Claims - Cats

- Repels and kills ticks, including [(Deer)(Black-legged)] ticks, (Ixodes scapularis) (vector of Lyme disease and anaplasmosis), American dog ticks (Dermacentor variabilis) (vector of Rocky Mountain spotted fever, cytauxzoonosis, and ehrlichiosis), Brown dog ticks, (Rhipicephalus sanguineus) (vector of ehrlichiosis, anaplasmosis, babesiosis, and Rocky Mountain spotted fever), and Lone Star ticks (Amblyomma americanum) (vector of cytauxzoonosis and ehrlichiosis) (for 8 months)
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (Anaplasma phagocytophilium), Babesiosis (Babesia canis, B.spp.), Borreliosis (Borrelia burgdorferi), Ehrlichiosis (Ehrlichia canis, E. spp.), Cytauxzoonosis (Cytauxzoon felis), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (cat) vector borne diseases]
- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (Anaplasma phagocytophilium), Babesiosis (Babesia canis, B. spp.), Borreliosis (Borrelia burgdorferi), Ehrlichiosis (Ehrlichia canis, E. spp.), Cytauxzoonosis (Cytauxzoon felis), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (cat) vector borne diseases]
- Kills [(Deer)(Black-legged)] ticks (, which may vector Lyme disease).
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever)
- Kills all (life) (blood feeding) stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (intitial) application

Date: 02/17/14 Supersedes: 05/29/13 Page 12 of 14

• Prevents tick infestations within 48 hours after (initial) application

- [(Kills)(Repels)] ticks in 6 hours after (initial) efficacy has been obtained
- Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours
- Protects against all types of ticks (attacking cats)
- Protects your (cat)(and/or)(kitten) from all types of ticks (for 8 months)
- Easy, effective [(treatment and prevention)(control)] of ticks and fleas

#### Flea Claims - Cats

- (Rapidly/Quickly) Kills fleas on cats within [24] hours and continues to prevent infestations (for 8 months)
- Kills and repels fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation (lasting 8 months)
- Seresto aids in control of flea larvae in the cat's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) (brand name)]-treated cat.
- Aids in the control of flea larvae in the cat's immediate surroundings
- Protects your (cat)(and/or)(kitten) from fleas (for 8 months)
- For the treatment and prevention of flea infestations on your cat (and in your cat's immediate surroundings)
- One treatment prevents further flea infestations (for 8 months)
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Treatment with [(PNR 1427)(brand name)(the collar)(this product)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]
- For prevention and treatment of flea infestation(s) for 8 months
- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on cats
- Treatment with [(PNR 1427)(brand name) (the collar)(this product)] kills fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Efficacy against fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in cats

#### Flea & Tick Claims - Cats

• REPELS AND kills fleas and ticks on cats and kittens 10 weeks of age and older

Page 13 of 14

REPELS AND kills fleas and ticks

## Optional/Alternative Marketing Claims – General

- Protects against ticks and fleas for 8 months
- (8-month) [(protector band)(pet collar)(collar)]
- [(Kills)(Protects)] against ticks and fleas for 8 months
- (Make sure to) replace (the) collar after 8 months [for year-round tick and flea (control)(prevention)]
- Remains effective after bathing or swimming
- Remains effective following shampooing, swimming or after rain
- [(Wetness)(Moisture)] does not reduce the collar's effectiveness
- No need to remove (the) collar while bathing pet
- No need to remove collar when (your) pet goes swimming or [(gets bathed)(bathing)]
- [(Seresto)(PNR 1427 Insecticide) (Brand name) (This product)(The collar)] is [(water resistant)(waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for fleas and 7 months for ticks.
- Fragrance-free
- Odorless
- No (noticeable) odor
- Non-greasy
- Easy to use
- (Easy)(convenient)(to use)(to apply)
- [(Graphite)(Gray)][Red][Yellow][(collar)(color)]
- (Adjustable)(convenient)(easy-to-apply) collar
- (Light) reflectors for added visibility (in the evening and at night)
- (Three) (3) (visibility) reflector clips (included)(for added pet visibility)
- (Snap-on) reflectors (included) for added (night-time)(pet)(visibility)
- One collar per animal (to be fastened around the neck)
- Contains one collar
- Sustained release technology for long-lasting flea and tick control for 8 months
- [(Patented)(Bayer)(technology) (polymer)(matrix)(system)] ensures that both active [(substances)(ingredients)] are (slowly) (and continuously) released (in low concentrations).
- (Patented) (Bayer) (Polymer) Matrix: [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)

Date: 02/17/14 Supersedes: 05/29/13

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• [(Sustained)(Slow)(Steady)(Continuous)] [(release)(distribution)] technology ensures that both active [(substances)(ingredients)] are (slowly) (and continuously) released (in low concentrations).

- [(Sustained)(Slow)(Steady)(Continuous)] [(release)(distribution)] technology: [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)
- (Depot effect:) [Active (substances)(ingredients)] stored inside the polymer matrix and gradually released over time]
- [(Continuous)(Even distribution)(Steady)] release) of active [(substances)(ingredients)] (over 8 months)
- (Continuous) flea and tick protection (over 8 months)
- Contains [(Patented)(Bayer) (polymer)(matrix)(system)]
- Contains [(sustained)(slow)(steady)(continuous)] [(release)(distribution)] technology
- No activation needed
- Use[(this)(attached)(included)] calendar sticker to remind you when your [(dog)(cat)(pet)] is due for its next application.
- [(Sustained)(Slow)(Steady)(Continuous)] [(release)(distribution)] technology for [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)

# Optional/Alternative Marketing Claims – Combined label for small collar for use on small dogs and cats

For external use on small dogs and cats only



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

April 3, 2014

Mr. J. Todd Frank Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Subject: Notification – Revised Marketing Claims

PRN 1427 Insecticide

EPA Registration Number: 11556-155 Date of Submission: February 20, 2014

Dear Mr. Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated February 20, 2014 for the product PRN 1427 Insecticide. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested does not clearly fall within the scope of PRN 98-10.

Please be advised that PRNs are provided as guidance; they are not considered regulation by the Agency. Therefore, the RD reserves the right to make the above determination and concludes that this action must be process as an amendment. This request has been transferred to an amendment and our records have been updated accordingly.

If you have any questions, please call BeWanda Alexander at 703-305-7460 or e-mail alexander.bewanda@epa.gov.

Granda aleuanders for Product Manager 10

Insecticide Branch

Registration Division (7505P)

#### Via Federal Express

February 20, 2014

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM 10

Subject: Revise optional text

PNR 1427 Insecticide (EPA Reg. No. 11556-155)

Dear Mr. Gebken:

Please find the enclosed Applications for Pesticide Notification. Included is one copy of the highlighted label, and copy of the unhighlighted labels for the subject product.

As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is revising claim statements. No new claims are made.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

If you have any questions, please do not hesitate to call (913) 268-2585.

Sincerely,

9, Tuck Frank J. Todd Frank

Regulatory Affairs Consultant

todd.frank@bayer.com

Enclosures:

1) PNR 1427 Insecticide - Application w/att.



Please read instructions on reverse before co ting form		Form A	pprove	MB No. 20	70-0060	T (HRE LOTTE		
SEPA Environmental Protes Washington, D	ncy Registration Amendment  X Other				OPP Identifier Number			
Applic	cation for P	esticide - S	ection					
1, Company/Product Number 11556-155		2. EPA Product A Richard Gebke				oposed Classification		
4. Company/Product (Name) PNR 1427Insecticide		PM# Team Number 10				None Restricted		
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390  Check if this is a new address	O	(b)(i), my produ to: EPA Reg. No Product Nam	oct is sim	ilar or identi	cal in co	FIFRA Section 3(c)(3) omposition and labeling		
	Sect	tion - II						
Amendment - Explain below.  Resubmission in response to Agency letter dated		Final printed labels in response to Agency letter dated "Me Too" Application.  Other - Explain below.						
E-mail Contact: todd.frank@bayer.com  1. Material This Product Will Be Packaged In:	Sect	ion - III						
Child-Resistant Peckaging  Yes*  No  Certification must be submitted  Unit Packaging  Yes  No  Void Packaging  Unit Packaging  Yes  No. p.  Unit Packaging wgt.	er If "Yes"		Specify)					
3. Location of Net Contents Information 4. Size(	s) Retail Contain	ier	5. Lo	On Label On Label		ons npanying product		
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled	□ •	ther					
		on - IV						
1. Contact Point (Complete items directly below for identity	fication of individ	dual to be contact	ed, if nec	essary, to pro	cers this	application.)		
Name J. Todd Frank	Telephone 913-268-			No. (Incluse Area Code) -2585				
Cer I certify that the statements I have made on this form I acknowledge that any knowingly false or misleading both under applicable law.						6. Date Application Received (Stamped)		
2. Signature	3. Title							
9.1000 Frul	Regulato	egulatory Affairs Consultant						
4. Typed Name	5. Date	ate						
J. Todd Frank	02/20/20	/2014				1		



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 17, 2013

Mr. Douglas A. Spilker, Ph.D. Bayer Healthcare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Subject:

Amendment: Rebuttal to Efficacy Review.

PNR 1427 Insecticide EPA Reg. No. 11556-155

Your Submission Dated July 3, 2013

Dear Mr. Spilker:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander at Alexander.bewanda@epa.gov or (703) 305-7460.

Sincerely, Je Dancia Weyander Ger

Richard Gebken

Product Manager Team 10

Insecticide Branch

Registration Division (7505P)

Enclosure

Reason To Issue: Propose revision of claims and other minor label additions.

Date: 05/29/13
Supersedes: 02/14/13, and 03/12/12
Page 1 of 15

Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

#### PNR1427 Insecticide

Alternate Brand Names: Seresto Small Dog; Seresto Large Dog; Seresto Cat

#### Optional Language for Small Collar

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]]

-or-

[For 8-month prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older]

-or-

ACCEPTED

DEC 17 2013
Under the Federal Insecticide.
Fungicide, and Rodenticide Act, as amended, for the pesticide
Registered under
EPA Reg. No. 1556-155

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]] [and/or] prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older]

## Optional Language for Large Collar:

[For 8-month prevention and treatment of ticks, fleas and lice for 8 months on (large) dogs and puppies 7 weeks of age and older and above [(18 lbs.)(8 kg)] [body weight]]

• [Selected optional label claims bulleted here from pages 9 to 15]

ACTIVE INGREDIENTS:	
Flumethrin *	4.5%
Imidacloprid	10.0%
OTHER INGREDIENTS	85.5%
Total	100%

<sup>\*</sup>Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

Net Contents: (X) Collar	(s) – XX oz. (XX grams)
EPA Reg. No. 11556-155	EPA Est. No. 11556-TBD

Reason To Issue:

Propose revision of claims and other minor label

additions.

Date: 05/29/13

Supersedes: 02/14/13,

and 03/12/12 Page 2 of 15

Manufactured For

Bayer Health Care LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA

Made in Germany

#### READ THE ENTIRE LABEL BEFORE USE

[For small collar: USE ON [(DOGS)(CATS)]]

-or-

[For small collar: USE ON SMALL DOGS and CATS]

-or-

[For large collar: USE ONLY ON DOGS]

#### DO NOT OPEN UNTIL READY TO USE DO NOT LET CHILDREN PLAY WITH THIS COLLAR [OR REFLECTORS]

# KEEP OUT OF REACH OF CHILDREN [CHOKING HAZARD - CONTAINS SMALL PARTS]

See [(back panel)(insert)] for Directions for Use.

#### **HOT LINE NUMBER**

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS, call 1-800-422-9874.
- For medical emergencies involving ANIMALS, call 1-800-422-9874.

additions.

Date: 05/29/13 Supersedes: 02/14/13, and 03/12/12

and 03/12/12 Page 3 of 15

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

#### HOW TO APPLY

One collar per animal to be fastened around the neck.

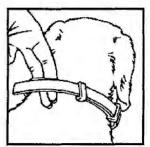
Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar. Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight or leaving it too loose. As a guide, it should be possible to only insert 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Collar length of greater than (1/one/an) inch (2 cm) beyond the loop(s) should be cut off unless it is on a growing [(puppy)(kitten)], where some additional length may be needed for adjustment as the animal grows.

[After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.]

#### Optional Visuals:

#### Dog









Reason To Issue:

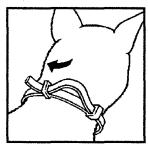
Propose revision of claims and other minor label additions.

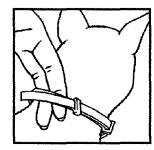
Date: 05/29/13 Supersedes: 02/14/13,

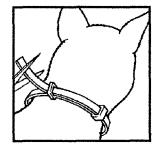
and 03/12/12 Page 4 of 15

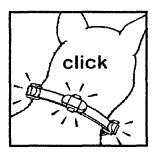
- or -











The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when [(puppies)(kittens)] are rapidly growing.

This collar is designed with a release[(system)(mechanism)]. In the unlikely event of a [(dog)(cat)(pet)] being trapped, the [(dog's)(cat's)(pet's)] own strength is sufficient to widen the collar to allow for quick release.

Replace the collar after 8 months for (optimal) (continuous) flea and tick protection.

#### PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

[(PNR 1427 Insecticide)(Brandname)(This product)(The collar)] kills existing flees on [(dogs)(cats)] within 24 hours. Reinfesting fleas are killed within 2 hours with projection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in control of flea larvae in the [(dog's)(cat's)] surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) treated [(dog)(cat)].

Reason To Issue: Propose revision of claims and other minor label

additions.

Date: 05/29/13 Supersedes: 02/14/13,

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Ticks already on the [(dog)(cat)] prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the [(dog)(cat)]. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours.

(Kills lice on dogs.)

Aids in the treatment (and control) of Sarcoptic mange on dogs.

[(Seresto) (PNR 1427 Insecticide) (This product)(The collar)] is [(water resistant) (waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for flea control and reduced to 7 months for tick control.

Occasionally scratching may be observed in animals that are not used to wearing collars during the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. For further guidance regarding individual animal sensitivities, see information below.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar (or reflectors,) or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. [Choking hazard. Contains small parts]. Do not place collar [or reflectors] in mouth. Not intended for use on humans.

For external use on [(dogs)(and)(cats)] only. Do not use on other animals. [(Do not use on puppies under seven weeks of age.)(Do not use on kittens under ten (10) weeks of age.)] Do not get this product in [(dog's)(cat's)] eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or mursing

Reason To Issue:

Propose revision of claims and other minor label additions.

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animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. Rarely, mild application site reactions may occur, such as scratching, redness and hair loss, which usually recover within 1 to 2 weeks without the need for collar removal. In some cases, a temporary collar removal and bathing may be recommended until symptoms have disappeared. In very rare cases, application site reactions such as dermatitis, inflammation, eczema or lesions may occur. In these instances, collar removal is recommended. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your [(dog)(or)(cat)] is experiencing an adverse event, contact your veterinarian and, call 1-800-422-9874.

The patented [(sustained)(slow)(steady)(continuous)][(release)(distribution)] technology ensures that both active [(substances) (ingredients)] are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active [(substances)(ingredients)] are present in the [(cat's)(and/or)(dog's)] haircoat during the entire [(protection)(efficacy)] period. The active [(substances)(ingredients)] spread from the site of direct contact over the skin surface.

#### [INSERT DIAGRAM THAT DEPICTS RELEASE FROM MATRIX.]

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Do not use container for food storage or other purposes.

**Pesticide Storage**: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of pouch and expired collar in trash. Outer container may be recycled or disposed of in trash.

#### LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include

Reason To Issue: Propose revision of claims and other minor label

additions.

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consequential commercial damages such as loss of profits or values, etc. [The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.]

Reason To Issue:

Propose revision of claims and other minor label

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#### Pouch Label

[(PNR 1427 Insecticide)(Brand name)]

4.5% flumethrin 10.0% imidacloprid

Do not let children play with this collar (or reflectors).

FOR USE ON (CATS)(DOGS)(CATS & DOGS)

See (outer container/leaflet/insert) for complete label information.

Do not open until ready to use.

BAYER HealthCare LLC, Animal Health Division

EPA Reg. No. 11556-155 EPA Est. No. 11556-TBD

Lot No. 0000000

#### Calendar Reminder Sticker

Use[(this)(attached)(included)] calendar sticker to remind you when your [(dog)(cat)(pet)] is due for its next application.

[(PNR 1427 Insecticide)(Brand name)]

Make sure to replace collar
after 8 months

Mobius Loop on outer container

Fe

Package

additions.

Date: 05/29/13 Supersedes: 02/14/13,

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Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

# Optional/Alternative Marketing Claims - Dogs

#### General Claims - Dogs

- Two active [(substances)(ingredients)] provide dual action against ticks, fleas, and lice (on dogs)
- For use on dogs and puppies 7 weeks of age and older
- Tick, (and) flea (and lice) (prevention)(control)(and) treatment for dogs 7 weeks of age or older
- [(PNR 1427)(Brand name)(This product)] is indicated for the prevention and treatment of ticks, fleas and lice on dogs and puppies (7 weeks of age and older)
- [Effective][Long-lasting] [protection] against ticks and fleas for 8 months
- [Effective][Long-lasting] [protection] against ticks, fleas and lice for 8 months
- Kills (and repels) ticks, (and) kills fleas (for 8 months)
- Reliable 8-month protection against ticks, and fleas on dogs (and puppies)
- Reliable 8-month protection against ticks, fleas and lice on dogs (and puppies)
- [3-way] protection against fleas, ticks and lice
- 8-month protection against ticks and fleas
- 8-month protection against ticks, fleas and lice
- For (small) dogs up to [(18 lbs.)(8 kg)] [body weight]
- For (large) dogs above [(18 lbs.)(8 kg)] [body weight]
- For external use on dogs
- For [(small dogs and puppies)(large dogs)]
- Fully effective within 48 hours after initial application of collar

#### Tick Claims - Dogs

- Repels and kills ticks for 8 months, including [(Deer)(Black-legged)] ticks, (*Ixodcs scapularis*) (vector of Lyme disease and anaplasmosis), American dog ticks, (*Dermacentor variabilis*) (vector of Rocky Mountain spotted fever and ehrlichiosis), Brown dog ticks, (*Rhipicephalus sanguineus*) (vector of ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis, and Rocky Mountain spotted fever), and Lone Star ticks (*Amblyomma americanum*) (vector of ehrlichiosis)
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (*Anaplasma phagocytophilium*), Bartonellosis (*Bartonella vinscnii, Bartonella spp.*), Babesiosis (*Babesia canis*, *B. gibsoni*), Borreliosis (*Borrelia burgdorferi*), canine hemoplasmosis (*Mycoplasma haemocanis*), Ehrlichiosis (*Ekrlichia*)

Reason To Issue:

Propose revision of claims and other minor label additions.

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canis, E. chaffeensis, E. ewingii), Hepatozoonosis (Hepatozoon canis and H. americanum), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (canine) vector borne diseases]

- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (Anaplasma phagocytophilium), Bartonellosis (Bartonella vinsonii, Bartonella spp.), Babesiosis (Babesia canis, B. gibsoni), Borreliosis (Borrelia burgdorferi), canine hemoplasmosis (Mycoplasma haemocanis), Ehrlichiosis (Ehrlichia canis, E. chaffeensis, and E. ewingii), Hepatozoonosis (Hepatozoon canis and H. americanum), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (canine) vector borne diseases]
- Kills [(Deer)(Black-legged)] ticks (, which may carry Lyme disease and Anaplasmosis)
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever and Ehrlichiosis)
- Kills all [(life)(blood feeding)] stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (initial) application
- Prevents tick infestations within 48 hours after (initial) application
- [(Kills)(Repels)] ticks in 6 hours after (initial) efficacy has been obtained
- Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours
- Protects against all types of ticks (attacking dogs)
- Protects your (dog)(and/or)(puppy) from all types of ticks (for 8 months)
- Easy, effective [(treatment and prevention)(control)] of ticks, (and) fleas (,and lice)

#### Flea Claims - Dogs

- (Rapidly/Quickly]) Kills fleas on dogs within [24] hours and continues to prevent infestations for 8 months
- Kills and repels fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months
- Seresto aids in control of flea larvae in the dog's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide)]-treated dog.
- Aids in the control of flea larvae in the dog's immediate surrounding:
- Protects your (dog)(and/or)(puppy) from fleas (for 8 months)
- For the treatment and prevention of flea infestations [on your dog (and in your dog's immediate surroundings)]
- One treatment prevents further flea infestations (on dogs) for 8 months
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs

Reason To Issue: Propose revision of claims and other minor label

additions.

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- Prevents fleas on treated dogs from infesting (reinfesting) your home
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]
- For prevention and treatment of flea infestation(s) for 8 months
- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on dogs
- Kills cat fleas (*Ctenocephalides felis*,) dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on dogs
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas that may vector tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii*, *Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Efficacy against fleas that may vector tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii, Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in dogs

#### Lice & Other Efficacy Claims - Dogs

- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice (infestations)
- Controls existing [(biting) (chewing)] lice infestations
- Treats, prevents and controls [(biting) (chewing)] lice (infestations)
- Provides effective control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations of [(biting) (chewing)] lice
- Aids in the treatment (and control) of Sarcoptic mange on dogs

## **Optional/Alternative Marketing Claims – Cats**

#### **General Claims - Cats**

- Two active [(substances)(ingredients)] provide dual action against ticks and fleas (on cats)
- For use on cats and kittens 10 weeks of age and older
- [Effective][Long-lasting] [ protection] for 8 months
- Tick, (and) flea (prevention)(control)(and) treatment for kittens 10 weeks of age or older

Reason To Issue: Propose revision of claims and other minor label

additions.

Date: 05/29/13 Supersedes: 02/14/13,

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- Tick and flea treatment for cats and kittens 10 weeks of age and older
- [(PNR 1427)(Brand name) (The collar)(This product)] is indicated for the prevention and treatment of ticks and fleas on cats and kittens (10 weeks of age and older)
- Kills (and repels) ticks and kills fleas (for 8 months)
- (Reliable) (8-month) protection against ticks and fleas [on cats (and kittens)]
- [Dual] [2-way] protection against ticks and fleas
- For external use on cats
- For cats and kittens
- Fully effective within 48 hours after initial application of collar

#### **Tick Claims - Cats**

- Repels and kills ticks, including [(Deer)(Black-legged)] ticks, (Ixodes scapularis) (vector of Lyme disease and anaplasmosis), American dog ticks (Dermacentor variabilis) (vector of Rocky Mountain spotted fever, cytauxzoonosis, and ehrlichiosis), Brown dog ticks, (Rhipicephalus sanguineus) (vector of ehrlichiosis, anaplasmosis, babesiosis, and Rocky Mountain spotted fever), and Lone Star ticks (Amblyomma americanum) (vector of cytauxzoonosis and ehrlichiosis) (for 8 months)
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (*Anaplasma phagocytophilium*), Babesiosis (*Babesia canis*, *B.spp.*), Borreliosis (*Borrelia burgdorferi*), Ehrlichiosis (*Ehrlichia canis*, *E. spp.*), Cytauxzoonosis (*Cytauxzoon felis*), and Rickettsiosis (*Rickettsia rickettsii*) [,which are types of (cat) vector borne diseases]
- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (Anaplasma phagocytophilium), Babesiosis (Babesia canis, B. spp.), Borreliosis (Borrelia burgdorferi), Ehrlichiosis (Ehrlichia canis, E. spp.), Cytauxzoonosis (Cytauxzoon felis), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (cat) vector borne diseases]
- Kills [(Deer)(Black-legged)] ticks (, which may vector Lyme disease)
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever)
- Kills all (life) (blood feeding) stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (intitial) application
- Prevents tick infestations within 48 hours after (initial) application
- [(Kills)(Repels)] ticks in 6 hours after (initial) efficacy has been obtained
- Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours
- Protects against all types of ticks (attacking cats)
- Protects your (cat)(and/or)(kitten) from all types of ticks (for 8 months)

additions.

Date: 05/29/13

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• Easy, effective [(treatment and prevention)(control)] of ticks and fleas

#### Flea Claims - Cats

- (Rapidly/Quickly) Kills fleas on cats within [24] hours and continues to prevent infestations (for 8 months)
- Kills and repels fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation (lasting 8 months)
- Seresto aids in control of flea larvae in the cat's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) (brand name)]-treated cat.
- Aids in the control of flea larvae in the cat's immediate surroundings
- Protects your (cat)(and/or)(kitten) from fleas (for 8 months)
- For the treatment and prevention of flea infestations on your cat (and in your cat's immediate surroundings)
- One treatment prevents further flea infestations (for 8 months)
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Treatment with [(PNR 1427)(brand name)(the collar)(this product)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]
- For prevention and treatment of flea infestation(s) for 8 months
- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on cats
- Treatment with [(PNR 1427)(brand name) (the collar)(this product)] kills fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Efficacy against fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in cats

### **Optional/Alternative Marketing Claims – General**

• Protects against ticks and fleas for 8 months

Reason To Issue: Propose revision of claims and other minor label

additions.

Date: 05/29/13 Supersedes: 02/14/13,

and 03/12/12 Page 14 of 15

- (8-month) [(protector band)(pet collar)(collar)]
- [(Kills)(Protects)] against ticks and fleas for 8 months
- (Make sure to) replace (the) collar after 8 months [for year-round tick and flea (control)(prevention)]
- Remains effective after bathing or swimming
- Remains effective following shampooing, swimming or after rain
- [(Wetness)(Moisture)] does not reduce the collar's effectiveness
- No need to remove (the) collar while bathing pet
- No need to remove collar when (your) pet goes swimming or [(gets bathed)(bathing)]
- [(Seresto)(PNR 1427 Insecticide) (Brand name) (This product)(The collar)] is [(water resistant)(waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for fleas and 7 months for ticks.
- Fragrance-free
- Odorless
- No (noticeable) odor
- Non-greasy
- Easy to use
- (Easy)(convenient)(to use)(to apply)
- [(Graphite)(Gray)][Red][Yellow][(collar)(color)]
- (Adjustable)(convenient)(easy-to-apply) collar
- (Light) reflectors for added visibility (in the evening and at night)
- (Three) (3) (visibility) reflector clips (included)(for added pet visibility)
- (Snap-on) reflectors (included) for added (night-time)(pet)(visibility)
- One collar per animal (to be fastened around the neck)
- Contains one collar
- [(Patented)(Bayer)(technology) (polymer)(matrix)(system)] ensures that both active [(substances)(ingredients)] are (slowly) (and continuously) released (in low concentrations).
- (Patented) (Bayer) (Polymer) Matrix: [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)
- [(Sustained)(Slow)(Steady)(Continuous)] [(release)(distribution)] technology ensures that both active [(substances)(ingredients)] are (slowly) (and continuously) released (in low concentrations).

Reason To Issue: Propose revision of claims and other minor label

additions.

Date: 05/29/13

Supersedes: 02/14/13, and 03/12/12 Page 15 of 15

- [(Sustained)(Slow)(Steady)(Continuous)] [(release)(distribution)] technology: [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)
- (Depot effect:) [Active (substances)(ingredients)] stored inside the polymer matrix and gradually released over time]
- [(Continuous)(Even distribution)(Steady)] release) of active [(substances)(ingredients)] (over 8 months)
- (Continuous) flea and tick protection (over 8 months)
- Contains [(Patented)(Bayer) (polymer)(matrix)(system)]
- Contains [(sustained)(slow)(steady)(continuous)] [(release)(distribution)] technology
- No activation needed
- Use[(this)(attached)(included)] calendar sticker to remind you when your [(dog)(cat)(pet)] is due for its next application.

# Optional/Alternative Marketing Claims – Combined label for small collar for use on small dogs and cats

For external use on small dogs and cats only



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

#### MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

Date: December 13, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

#### This amendment did not go to the contractor as it was a rebuttal to previous reviews.

DP barcode: 413954 Decision no.: 48065 Submission no: 937974

Action code: R340

Product Name: PNR1427 Insecticide EPA Reg. No or File Symbol: 11556-155 Formulation Type: Impregnated pet collar

Ingredients statement from the label with PC codes included: 4.5% flumethrin (pc code:

036007) and 10% imidacloprid (pc code: 129099)

Application rate(s) of product: one collar per cat or dog

Use pattern: ectoparasiticide pet collar

OCSPP/OPPTS Guidelines: OPPTS 810.3300.

I. Action Requested: Review rebuttal to previous DER by Clayton Myers. Bayer also pointed to some other MRIDs.

II. Background: Registrant makes an argument for adding the 8-month claim for chewing lice based on previously reviewed product specific data and the Agency's approach to the interpretation of such data for registered Merial products.

#### III. Study Review:

No new studies were submitted.

#### 1. Eight month lice claim

For the 8-month lice claim, the registrant referred to data from previously reviewed MRID4824013 in which dogs that were naturally infested with lice were used. Once the

infestation was eliminated they would have needed to be reinfested naturally to do a residual evaluation. Second, MRID48240136 was referenced where hair from dogs wearing the collars for eight months was analyzed for imidacloprid content. The content of imidacloprid was higher on the collected hair than on animal dosed with another product containing imidacloprid that controlled lice at a lower rate of application.

#### 2. Speed of kill and repellency of ticks on cats.

The claims for six-hour speed of tick kill and tick repellency on cats are acceptable. However, the efficacy measurements weren't made until the collars were on the cats or dogs for two days. If the product begins working at 48 hours then we need to account for that in the label claims or directions for use.

#### IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

1. The label amendment is acceptable.

# Bayer HealthCare Animal Health



Bayer HealthCare LLC

Shawnee Mission, KS 66201-0390

Animal Health P.O. Box 390

Via Federal Express

July 3, 2013

Office of Pesticide Programs (7504P) – (REGFEE – R340) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention:

Mr. Richard Gebken/PM10 Registration Division (7505P)

Subject: PNR1427 Insecticide (EPA Reg. No. 11556-155; ABN: Seresto)

Amendment to revise claims and make other label changes (PRIA R340; Amendment requiring data review within RD)

Dear Mr. Gebken:

Please find attached revised draft labeling, an application and the appropriate attachments to request acceptance of revised labeling for the subject product. No additional data are being submitted with this application, but we are requesting that the Agency re-review previously submitted data that was provided with the original submission that supported the initial registration of the product. The details of this request, including an outline of the label revisions, are found in the 2-page attachment to the application and in the document entitled "ATTACHMENT A: Seresto Label Issues." A "red-lined" version of the draft label showing the changes is also included.

If you have any questions, please do not hesitate to call me at 913-268-2751.

Sincerely

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug.Spilker@Bayer.com

#### Attachments:

- 1. Application for Registration, dated 7/3/2013, with 2-page attachment
- 2. ATTACHMENT A: Seresto Label Issues
- 3. Efficacy Review (Out date 5-9-02) for EPA Reg. No. 65331-5
- 4. Product Performance Data Evaluation Record, dated 3/14/2012 (for File Symbol 11556-RLL)
- 5. PNR1427 Insecticide, revised draft labeling with red-lining, dated 5/29/13 (1 copy)
- 6. PNR1427 Insecticide, revised draft labeling, dated 5/29/13 (5 copies)
- 7. PAY GOV PRIA Payment Confirmation

#### Alexander, BeWanda

From:

Alexander, BeWanda

Sent:

Tuesday, October 22, 2013 2:18 PM

To:

Alexander, BeWanda

Subject:

FW: PRIA Actions Missed due to Shutdown

Based on the guidance below this action was not renegotiated and the PRIA date was missed due to the government shutdown and its cascading effects of being closed for 16 days. This action is now closed—"date"

From: Rossi, Lois

Sent: Tuesday, October 22, 2013 12:34 PM

To: Kenny, Daniel; McCall, Deborah; 'Cynthia Giles-Parker'; Laws, Meredith

Subject: PRIA Actions Missed due to Shutdown

For the PRIA actions due in Oct and Nov we will **not** be doing renegotiations. We will try to get these actions caught up by the end of November EXCEPT for new uses and new chemicals. For new chems and new uses due in Oct and Nov we will not be doing renegotiations but I will be asking you to project a date to complete the action. We will discuss further in staff tomorrow. Thanks

Lois Rossi, Director Registration Division Office of Pesticide Programs U.S. EPA 703-308-8162 (office) 703-305-6920 (Fax)

# **21-Day Screen of Amendment** (Completed by Contractor)

21-day Expires on 7/09/13

Document Part Of: 11556-155
MRID, If Any: 1/4

Content Screen: Recommended to Pass/Fail

11-3 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Steve Schaible

# PRIA 3 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) September 2012

21 Day Screen Start Date: 7-8-13	Septemo	CI 2012		
-	B.B.	Date	e7-9-13	Fee Paid: Yes 🗸
Division management contacted on issues	No	Yes	Date	

Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)					X	
2	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use	only.				_* - ' xi <sub>v</sub> -
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and					X
	Data Matrix (EPA Form 8570-35) both internal and external completed and signed (N/A if 100% repack)	pies ( <u>PR</u>	<u>98-5</u> )			X
5		yes	no		a.	
3	a) Selective Method (Fee category experts use)  b) Cite-All (Fee category experts use)			913		
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5					+
8	Notice of Filing included with petitions					

9	If applicable for conventional applications, <u>reduced risk rationale</u>		*
	Required Data and/or data waivers. See Footnote C.		
	a) List study (or studies) not included with application		
			:
10			
		· 	

**Comments:** 

There are no studies associated with this amendment.

TU

#### \* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency even if a product is currently registered by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="mailto:inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the <a href="mailto:Chief of Microbial Pesticides Branch">Chief of Microbial Pesticides Branch</a>.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### Unapproved Inerts Identified on CSFs

#### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
- 3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
- 4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 9, 2013

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-480685

EPA File Symbol or Registration Number: 11556-155

Product Name: PNR1427 INSECTICIDE

EPA Receipt Date: 08-Jul-2013 EPA Company Number: 11556

Company Name: BAYER HEALTHCARE LLC

DOUGLAS A. SPILKER, Ph.D. BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION PO Box 390 SHAWNEE MISSION, KS 66201-0390

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

#### Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

AMENDMENT; NON-FAST TRACK; REVIEW WITHIN RD, E.G. PRECAUTIONARY LABELING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

This package includes the following	for Division
<ul><li>New Registration</li><li>● Amendment</li></ul>	○ AD ○ BPPD ○ RD
☐ Studies? ☐ Fee Waiver? ☐ volpay % Reduction:	Risk Mgr. 10
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	937974 11556-155 7/8/2013
This item is NOT subject to	FFS action.
Action Code:  Requested: R340  Granted: R340  Amount Due: \$ 3617	Parent/Child Decisions:
Inert Cleared for Intended Use  Reviewer:  Remarks:	Uncleared Inert in Product  Date: 7/9/13 -

#### Doug Spilker

From: paygovadmin@mail.doc.twai.gov

Sent: Wednesday, July 03, 2013 6:56 AM

To: Doug Spilker

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at <a href="mailto:pay.gov.clev@clev.frb.org">pay.gov.clev@clev.frb.org</a>.

Application Name: PRIA Service Fees Pay.gov Tracking ID: 25BE01KU Agency Tracking ID: 74471966367

Transaction Type: Sale

Transaction Date: Jul 3, 2013 7:55:59 AM

Account Holder Name: Douglas A . Spilker

Transaction Amount: \$3,617.00

Billing Address: 12707 Shawnee Mission Parkway

City: Shawnee State/Province: KS

Zip/Postal Code: 662161846

Country: USA

Card Type: MasterCard

Card Number: \*\*\*\*\*\*\*\*\*\*0576

Decision Number:

Registration Number: 11556-155

Company Name: Bayer HealthCare LLC, AH

Company Number: 11556

Action Code: R340

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



#### United States

	Registration
X	Amendmen
	Other
	J Carrot

OPP Identifier Number

<b>SEPA</b>	Environmental Washin	Protection ogton, DC 204		; <b>y</b>	X	Amenda Other	nent		
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4. Company/Product (Name PNR 1427 Insecticide			PI 1	<b>M#</b> 0				]	
5. Name and Address of Ap Bayer Healthcare LLC, P.O. Box 390 Shawnee Mission, KS (	Animal Health Divisi		(b	o)(i), my pro o:	duct is sim		ical in cc	mposition	ection 3(c)(3) n and labeling
			Section						
Amendment - Explain Resubmission in responsion in responsion - Explain  Explanation: Use addition PRIA Action: R340 - Lithis request, including document entitled "AT"	ponse to Agency letter of below.  nal page(s) if necessary abel Amendment to an outline of the lab	r. (For section revise clair	ms and ma	Agent Me 1 Other on (i.) ake other land in the 2-	cy letter dat Too" Applica r - Explain be abel chang page attac	stion. elow. ges; data rechment to the	eview wi	ication a	nd in the
we are requesting that  1. Material This Product Wil		ew previous	Section		man cond	act. doug.s	pliker@i	bayer.co	in .
Child-Resistant Packaging Yes No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt,	No. per container	Weter Sold	No	ng , per ntainer	2. Type of (	Metal Plastic Glass Paper	Specify)	
3. Location of Net Contents	Information Container	4. Size(s) Rat	ail Container		5. Lo	cation of Lab	el Directio	)ns	
6. Manner in Which Lebel is	Affixed to Product	Lithogi Peper Stencil	raph glued led		Other				
			Section	n - IV					
1. Contact Point (Complete	items directly below fo	r identification	n of individue	el to be conte	cted, if nec	essery, to pro	cess this	applicatio	n.)
Name Douglas A. Spilker,	Ph.D.		Title Manag	ger, EPA R	leg. Affairs			e No. (Incl 268-275	ude Area Code) 1
	oments i have made on t ny knowlingily false or n law.		all attachmen					Receiv	Application yed tamped)
2. Signature Darks	A. Gul		з. ты. Manager,	, EPA Re	g. Affairs	i			
4. Typed Name Douglas A. Spilker	, Ph.D.		5. Date	3 Ju	g 21	013			

Item	Page No.	Label revision	Comments
Α	3	Revised HOW TO APPLY to include: a) further discussion about the proper tightness of collar and b) leaving a little excess for rapidly growing puppies/kittens.	Non-substantive changes
В	4	Revision of the terms to describe the safety attributes of the collar to be a "release system/mechanism" rather than a "closure mechanism."	Mere word choice change to better describe this important safety feature of the collar.
С	5	Paragraph 3: Deleted the restriction that control of lice on dogs is only "for a month."	We request that this restriction be reconsidered and allow for the general claim of the control of this pest on dogs for the full 8 months. See <b>Attachment A</b> for a discussion of this topic.
D	5	Paragraph 3: Added that the control of Sarcoptic mange is on dogs only.	It is our understanding that is pest is not found on cats.
E	5	Paragraph 4: Added a clarifying statement regarding the effect of swimming on the efficacy of the collar; i.e. 5 months for flea control and reduced to 7 months for tick control.	Reference is made to the "PRODUCT PERFORMANCE DATA EVALAUTION RECORD, dated March 14, 2012, for the subject product. The summary for MRID 48240118 (item "e" of DER) states that "For dogs that swim once per month, flea claims are limited to 5 months and tick claims to 7 months."
F	5	Paragraph 5: revised wording for readability, and to point user to additional information on individual animal sensitivities later in the label. This results in all such information together in one area of the label.	See Page 6 for the "additional information" that has been added on individual animal sensitivities.
G	6	Paragraph 1: further elaboration of information on signs of individual animal sensitivities and recommended treatment.	Revisions based on feedback from actual use of collars in the marketplace.
Н	6	Paragraph 2: revised word choice regarding release attributes of collar.	Current text does not resonate with end- users, and more consumer friendly language has been added.
I	6	STORAGE AND DISPOSAL: added statement communicating that the container must not to be used for food storage or other purposes; added statement that outer container may be recycled.	
J	8	Added: a) text for a calendar reminder sticker to be included in container, and b) added a Mobius loop indicating that the outer package (Fe) can be recycled.	

Item	Page No.	Label revision	Comments
K	9	Added 3 claims that encompass the addition of the 8-month claim for lice on dogs.	See Item C above.
L	10	Includes "and repels" in third bullet under flea claims for dogs; this claim is already accepted for cats and the same data support both species (see page 13, bullet 2 under "Flea Claims – Cats.")	This was our over-sight and accidently left off the proposed label for dogs.
М	11	Revised bullets 6 & 7	Revised to use Agency preferred word "vector" instead of "transmit."
N	11	Deleted the restriction that control of lice on dogs is only "for a month."	See Item C above.
0	11	Added that the control of Sarcoptic mange is on dogs only.	See Item D above.
P	12	Added 2 marketing claims regarding speed of kill of ticks on cats.	These exact claims can be found under the tick section for dogs (bullets 8 & 9 of page 10); the data supporting the claims on dogs also supports this claim on cats - see Attachment A for further discussion.
Q	13	Deletion of the Sarcoptic mange claim on cats.	See item D above.
R	14	Added a clarifying statement regarding the effect of swimming on the efficacy of the collar; i.e. 5 months for flea control and reduced to 7 months for tick control.	See item E above.
S	14	Bullet 19: addition of the word "clips" after reflector to be more descriptive.	
Т	14	Bullet 25: revised claim regarding release attributes of collar.	See Item G above.
U	15	Bullet 1: revised claim regarding release attributes of collar.	See Item G above.
V	15	Bullet 6: revised claim regarding release attributes of collar.	See as Item G above.
W	15	Bullet 7: added statement that no activation of the collar is needed for it to work.	
X	15	Bullet 8: added label statement regarding the inclusion of a calendar sticker in the package. Calendar sticker text found on Page 8.	



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Washington, DC 20460. Do no	t send the form to this address.					
·	DATA MAT	TRIX	· 	·		· 
Date: August 8, 2013			EPA Re	g. No./File Symbol: 279-3155		Page 1 of 4
Applicant's/Registrant's Name a FMC Corporation- 1735 N	nd Address Market Street- Philadelphia, PA 19103 (215) 299-6608		Product Talsta	ır Nursery Flowable Inse	cticide/Miticide	
Ingredient Bifenthrin: (2 m	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-	-propenyl)-	-2,2-dim	nethylcyclopropane carboxy	vlate CAS# 82	657-04-3
Guideline Reference Number	Guideline Study Name	MRID N	lumber	Submitter	Status	Note
Series 870	Acute Toxicology	<del></del>				
870.1100	Acute Oral LD <sub>50</sub> – Rat	41413	602	FMC Corporation	OWN	
870.1200	Acute Dermal LD <sub>50</sub> – Rat	41413	603	FMC Corporation	OWN	
870.1300	Acute Inhalation LC <sub>50</sub> – Rat	41413	604	FMC Corporation	OWN	
870.2400	Primary Eye Irritation – Rabbit	41413	605	FMC Corporation	OWN	
870.2500	Primary Dermal Irritation – Rabbit	41413	606	FMC Corporation	OWN	
870.2600	Dermal Sensitization – Guinea Pig	41413	607	FMC Corporation	OWN	
Series 830	Product Chemistry					
830.1700	Preliminary Analysis	41413	601	FMC Corporation	OWN	
830.1550	Product Identity and Composition	41413	601	FMC Corporation	OWN	
830.1600	Description of Materials Used	41413	601	FMC Corporation	OWN	
830.1550	Product Identity and Composition	41413	601	FMC Corporation	OWN	
830.1600	Description of Materials Used to Produce the Product	41413	601	FMC Corporation	OWN	
830.1650	Description of Formulation Process	41413	601	FMC Corporation	OWN	
830.1670	Discussion of Formation of Impurities	41413	601	FMC Corporation	OWN	

Aulerda de Bonoman

Name and Title Melinda Bowman Product Registration Manager

Date August 8, 2013



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	DATA MAT	RIX				
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155			Page 2 of 4
Applicant's/Registrant's Name a FMC Corporation- 1735 N	nd Address Market Street- Philadelphia, PA 19103 (215) 299-6608		Product <b>Talsta</b>	ır Nursery Flowable Insec	ticide/Miticide	
Ingredient Bifenthrin: (2 m	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-	propenyl)	-2,2-dim	nethylcyclopropane carboxyl	late CAS# 826	57-04-3
Guideline Reference Number	Guideline Study Name	MRID	lumber	Submitter	Status	Note
830.1700	Preliminary Analysis	41413	601	FMC Corporation	OWN	
830.1750	Certified Limits	41413	601	FMC Corporation	OWN	
830.1800	Enforcement Analytical Method	41413	601	FMC Corporation	OWN	
830.6302	Color	41413	601	FMC Corporation	OWN	
830.6303	Physical State	41413	601	FMC Corporation	OWN	
830.6304	Odor	41413	601	FMC Corporation	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals and Ions	41413	601	FMC Corporation	OWN	
830.6314	Oxidizing/Reduction; Chemical Incompatibility	41413	601	FMC Corporation	OWN	
830.6315	Flammability	41413	601	FMC Corporation	OWN	
830.6316	Explodability	41413	601	FMC Corporation	OWN	
830.6317	Storage Stability	41413	8601	FMC Corporation	OWN	
830.6319	Miscibility	41413	601	FMC Corporation	OWN	
830.6320	Corrosion Characteristics	41413	601	FMC Corporation	OWN	
830.6321	Dielectric Breakdown Voltage	41413	601	FMC Corporation	OWN	
830.7000	pH	41413	601	FMC Corporation	OWN	
Sulinda Se. 12	numan			nd Title Melinda Bowman ct Registration Manager	Date August 8, 20	13



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·	DATA MATE	RIX	, 		_
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		
Applicant's/Registrant's Name a FMC Corporation- 1735 N	nd Address Market Street- Philadelphia, PA 19103 (215) 299-6608	Prod Tals	<sup>uct</sup> star Nursery Flowable Inse	ecticide/Miticid	e
Ingredient Bifenthrin: (2 m	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-p	ropenyl)-2,2-0	dimethylcyclopropane carbox	ylate CAS# 82	2657-04-3
Guideline Reference Number	Guideline Study Name	MRID Numbe	r Submitter	Status	Note
830.7100	Viscosity	41413601	FMC Corporation	OWN	
830.7200	Melting Point/Melting Range	41413601	FMC Corporation	OWN	
830.7220	Boiling Point/Boiling Range	41413601	FMC Corporation	OWN	
830.7300	Density/Relative Density/Bulk Density	41413601	FMC Corporation	OWN	
Series 810	Product Performance				
810.3100	Six month residual claims – Fire Ants	44021901	FMC Corporation	OWN	
810.3100	Bifenthrin Control of Deer Ticks in Turfgrass	44137401	FMC Corporation	OWN	
810.3100	Bifenthrin Control of Dog Ticks in Turfgrass Public health pests	44137402	FMC Corporation	OWN	
810.3100	Media incorporation & drench / Japanese beetle & grub/Containerized plants	44637901	FMC Corporation	OWN	
810.3100	Media incorporation & drench / Black vine weevil / Containerized plants	44671701	FMC Corporation	OWN	
810.3300	Efficacy of Bifenthrin mound treatments for IFA control	44638801	FMC Corporation	OWN	
810.3300	Efficacy of Bifenthrin liquid applications	44891901	FMC Corporation	OWN	
810.3300	Evaluation of Bifenthrin and a Malathion spray	44891904	FMC Corporation	OWN	

Name and Title Melinda Bowman
Product Registration Manager
August 8, 2013



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		DATA MATR	IX			
Date: August 8, 2013			EPA Re	eg. No./File Symbol: 2	79-3155	Page 4 of 4
Applicant's/Registrant's Name an FMC Corporation- 1735 M	nd Address arket Street- Philadelphia, PA 19103	(215) 299-6608	Product Talsta		ble Insecticide/Mi	ticide
Ingredient Bifenthrin: (2 me	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-ch	loro-3,3,3-trifluoro-1-pr	openyl)-2,2-din	nethylcyclopropan	e carboxylate CAS	6# 82657-04-3
Guideline Reference Number	Guideline Study Name		MRID Number	Submitter	Status	Note

810.3300	Efficacy of direct spray applications of Bifenthrin liquid	44891905	FMC Corporation	OWN	
810.3300	Efficacy of direct spray applications of Bifenthrin liquid	44891907	FMC Corporation	OWN	
810.3300	Efficacy of direct spray applications of Bifenthrin liquid	44891908	FMC Corporation	OWN	
810.3400	Residual efficacy of Bifenthrin liquid applications	44891903	FMC Corporation	OWN	
810.3500	Efficacy of broadcast application of Bifenthrin	44891902	FMC Corporation	OWN	_
810.3500	Efficacy of direct spray applications of Bifenthrin liquid	44891906	FMC Corporation	OWN	

1 1 0	Name and Title Melinda Bowman	Date
Aulinda de Bruman	Product Registration Manager	August 8, 2013



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, SW

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	DATA MA	TRIX				
Date: August 8, 2013		EF	PA Re	g. No./File Symbol: 279-3155		Page 1 of 4
Applicant's/Registrant's Name a FMC Corporation- 1735 N	nd Address Market Street- Philadelphia, PA 19103 (215) 299-6608	100	roduct alsta	r Nursery Flowable Inse	cticide/Miticide	<u> </u>
Ingredient Bifenthrin: (2 m	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1	-propenyl)-2,2	2-dim	nethylcyclopropane carboxy	ylate CAS# 82	657-04-3
Guideline Reference Number	Guideline Study Name	MRID Num	nber	Submitter	Status	Note
				FMC Corporation	OWN	
				FMC Corporation	OWN	
				FMC Corporation	OWN	
				FMC Corporation	OWN	
				FMC Corporation	OWN	
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				FMC Corporation	OWN	
				FMC Corporation	OWN	
Aulinda de B	noman			nd Title Melinda Bowman	Date August 8, 20	113

Kulinda du Ponoman

Product Registration Manager

August 8, 2013

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	DATA MA	TRIX			
Date: August 8, 2013		EPA F	Reg. No./File Symbol: 279-3155		Page 2 of 4
Applicant's/Registrant's Name and Address FMC Corporation- 1735 Market Street- Philadelphia, PA 19103 (215) 299-6608  Product Talstar Nursery Flowable Insect		cticide/Miticid	e		
Ingredient Bifenthrin: (2 me	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1	-propenyl)-2,2-d	imethylcyclopropane carboxy	ylate CAS# 82	2657-04-3
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	Not Applicable
			FMC Corporation	OWN	Not Applicable
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	
			FMC Corporation	OWN	Not Applicable
			FMC Corporation		
			FMC Corporation	OWN	Not Applicable
			FMC Corporation	OWN	
Aulinda de B	nomen	10000000	and Title Melinda Bowman uct Registration Manager	Date August 8, 2	013



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	DATA	MATRIX			
Date: August 8, 2013		EPA Re	eg. No./File Symbol: 279	9-3155	Page 3 of 4
Applicant's/Registrant's Name a	nd Address farket Street- Philadelphia, PA 19103 (215) 299-660	8 Product	ar Nursery Flowabl	e Insecticide/Mitici	ide
Ingredient Bifenthrin: (2 m	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluo	ro-1-propenyl)-2,2-din	nethylcyclopropane	carboxylate CAS#	82657-04-3
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

FMC Corporation	OWN	
FMC Corporation	OWN	Not Applicable
FMC Corporation	OWN	Not Applicable
FMC Corporation	OWN	
FMC Corporation	OWN	1
FMC Corporation	OWN	
FMC Corporation	OWN	

1 1.0	Name and Title Melinda Bowman Date		,
Sulinda Si Broman	Product Registration Manager	August 8, 2013	



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	DAT	A MATRIX		·	
Date: August 8, 2013		EPA Re	eg, No./File Symbol: 279	-3155	Page 4 of 4
Applicant's/Registrant's Name a	nd Address Market Street- Philadelphia, PA 19103 (215) 299-6	Product 608 Talsta	t ar Nursery Flowabl	e Insecticide/Mitici	de
	ethyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-triflu		-		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

FMC Corporation	OWN	
FMC Corporation	OWN	

	Name and Title Melinda Bowman	Date	
Sulinda Se Bonoman	Product Registration Manager	August 8, 2013	



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	DAT	TA MATRIX			
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		Page 1 of 6
Applicant's/Registrant's Name and FMC Corporation- 1735 Ma	Address rket Street- Philadelphia, PA 19103 (215) 299-6	6608	Product Talstar Nursery Flowable Insec	cticide/Miticide	
Ingredient Bifenthrin: (2 methyl[1	,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)	-2,2-dimethylcyclopro	ppane carboxylate CAS# 82657-04-3		<u> </u>
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Series 870	Toxicology				
870.3100	90-day oral toxicity- rat	00141199	FMC Corporation	OWN	
870.3150	90-day oral toxicity- dog	00141200	FMC Corporation	OWN	
870.3700	Developmental toxicity (gavage)- rat	00154482	FMC Corporation	OWN	
870.3700	Developmental toxicity (gavage)- rat	00141210	FMC Corporation	OWN	
870.3700	Developmental toxicity (dietary)- rat	45322301	FMC Corporation	OWN	
870.3700	Developmental toxicity- rabbit	00145997	FMC Corporation	OWN	
870.3800	Multigeneration reproductive toxicity- rat	00157225	FMC Corporation	OWN	
870.4100	Chronic toxicity- dog	00163065	FMC Corporation	OWN	
870.4300	Chronic toxicity/Carcinogenicity- rat	00157226	FMC Corporation	OWN	
870.4200	Carcinogenicity- mouse	00157227	FMC Corporation	OWN	
870.6200a	Acute neurotoxicity- rat	44862102	FMC Corporation	OWN	
870.6200b	Subacute neurotoxicity- rat	44862103	FMC Corporation	OWN	
870.6300	Developmental neurotoxicity- rat	46750501 46750502	FMC Corporation	OWN	
870.3200	Dermal toxicity- rabbit	00141198	FMC Corporation	OWN	
870.3200	Dermal toxicity- rat	45280501	FMC Corporation	OWN	
Aulinda Sr. Br	wman_		Name and Title Melinda Bowman Product Registration Manager	Date August 8, 20	13

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	DATA	MATRIX		·	
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		Page 2 of 6
The second of th		Product Talstar Nursery Flowable Insecticide/Miticide			
Ingredient Bifenthrin: (2 methyl[	1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,	2-dimethylcyclopro	opane carboxylate CAS# 82657-04-3		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7485	Metabolism- rat	00163067	FMC Corporation	OWN	
870.7485	Metabolism- rat	40415102	FMC Corporation	OWN	
870.7485	Metabolism- rat	00163069	FMC Corporation	OWN	
870.7485	Metabolism- rat	00163070	FMC Corporation	OWN	
870.7485	Metabolism- rat	00163071	FMC Corporation	OWN	
870.7485	Metabolism- rat	00163066	FMC Corporation	OWN	
870.7485	Metabolism- rat	40415100	FMC Corporation	OWN	
870.7485	Metabolism- rat	00163068	FMC Corporation	OWN	
870.7600	Dermal penetration- rat	41917503	FMC Corporation	OWN	
870.7600	Dermal penetration- rat	41917502	FMC Corporation	OWN	
870.7600	Dermal penetration- rat	00163072	FMC Corporation	OWN	
870.7600	Dermal penetration- rat	41284202	FMC Corporation	OWN	
Series 860	Residue Chemistry				
860.1300	Nature of the Residue- Plants	00163075	FMC Corporation	OWN	
860.1300	Nature of the Residue- Plants	40257901	FMC Corporation	OWN	
860.1300	Nature of the Residue- Plants	40257902	FMC Corporation	OWN	
Aulinda de Br	wman_		Name and Title Melinda Bowman Product Registration Manager	Date August 8, 20	13

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•	DAT	TA MATRIX	•	•	•
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		Page 3 of 6
Applicant's/Registrant's Name and FMC Corporation- 1735 Ma	l Address arket Street- Philadelphia, PA 19103 (215) 299-6	6608	Product Talstar Nursery Flowable Insec	cticide/Miticio	de
Ingredient Bifenthrin: (2 methyl[1	1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)	-2,2-dimethylcyclopro	opane carboxylate CAS# 82657-04-3		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1300	Nature of the Residue- Livestock	00163076- 00163077	FMC Corporation	OWN	
860.1300	Nature of the Residue- Livestock	40384401- 40384405	FMC Corporation	OWN	
165-1	Rotational Crops	00163093 40414001	FMC Corporation	OWN	
860.1850	Confined rotational crop	42039601	FMC Corporation	OWN	
165-4	Fish Accumulation	00163094 00163095 40414001	FMC Corporation	OWN	
860.1900	Field accumulation	45306501	FMC Corporation	OWN	
Series 835	Environmental Fate Data				
161-1	Hydrolysis	00132539	FMC Corporation	OWN	
161-2	Photodegradation- Water	00163084 40414001	FMC Corporation	OWN	
161-3	Photodegradation- Soil	00163085	FMC Corporation	OWN	
162-1	Aerobic Soil Metabolism	00141202 00152266 00163086	FMC Corporation	OWN	
Aulinda Su. Bor	wman		Name and Title Melinda Bowman Product Registration Manager	Date August 8,	2013



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, SW

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Washington, DC 20460

	ם	ATA MATRIX	,		
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		Page 4 of 6
Applicant's/Registrant's Name and FMC Corporation- 1735 Ma	Address irket Street- Philadelphia, PA 19103 (215) 29	9-6608	Product Talstar Nursery Flowable Inse	cticide/Miticio	le
Ingredient Bifenthrin: (2 methyl[1	,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-proper	nyl)-2,2-dimethylcyclopro	opane carboxylate CAS# 82657-04-3		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		00163087 40414001			
162-2	Anaerobic Soil Metabolism	00163088	FMC Corporation	OWN	
163-1	Leaching/ Adsorption-Desorption	00163089	FMC Corporation	OWN	
163-2	Laboratory Volatility	00163090 40414001 40581601 41220601	FMC Corporation	OWN	
164-1	Soil Dissipation	00163091 40414001 40581601	FMC Corporation	OWN	
Series 850	Ecological Effects				
71-1	Avian Oral LD50- Quail	00132532	FMC Corporation	OWN	
71-1	Avian Oral LD50- Mallard	00132534	FMC Corporation	OWN	
71-2	Avian LC50- Quail	00132533	FMC Corporation	OWN	
71-2	Avian LC50- Mallard	00132535	FMC Corporation	OWN	
71-4	Avian Reproduction- Quail	00163097 00163098 40266301	FMC Corporation	OWN	
Aulinda de Bon	www		Name and Title Melinda Bowman Product Registration Manager	Date August 8, 2	2013



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	. DA	ATA MATRIX				
Date: August 8, 2013			EPA Reg. No./File Symbol: 279-3155		Page 5 of 6	
Applicant's/Registrant's Name and Address FMC Corporation- 1735 Market Street- Philadelphia, PA 19103 (215) 299-6608		Product Talstar Nursery Flowable Insecticide/Miticide				
Ingredient Bifenthrin: (2 methyl[1	,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propen	yl)-2,2-dimethylcyclopro	ppane carboxylate CAS# 82657-04-3			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
71-4	Avian Reproduction- Mallard	00163099 00163100	FMC Corporation	OWN		
72-1	Freshwater Fish LC50- Trout	00163156	FMC Corporation	OWN		
72-1	Freshwater Fish LC50- Bluegill	00132536	FMC Corporation	OWN		
72-2	Acute LC50 Freshwater Invertebrates	00132537	FMC Corporation	OWN		
72-3	Acute LC50 Estuarine- Mysid	00163102	FMC Corporation	OWN		
72-3	Acute LC50 Estuarine- Minnow	00163101	FMC Corporation	OWN		
72-3	Acute LC50 Estuarine- Oyster	00163103 40266501 40383502	FMC Corporation	OWN		
72-3	Acute LC50- Mollusc	40447601	FMC Corporation	OWN		
72-4	Fish Early Life Stage- Freshwater	40447601 41156501 42338801 41640501	FMC Corporation	OWN		
72-4	Fish Early Life Stage- Estuarine	40447601	FMC Corporation	OWN		
72-5	Fish Life Cycle	40447601 40791301 41032101	FMC Corporation	OWN		
Aulinda de Br	iman		Name and Title Melinda Bowman Product Registration Manager	Date August 8, 2	2013	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Form Approved OMB No. 2070-0060

DATA MATRIX						
Date: August 8, 2013 EPA Reg. No./File Symbol: 279-3					Page 6 of 6	
Applicant's/Registrant's Name and Address FMC Corporation- 1735 Market Street- Philadelphia, PA 19103 (215) 299-6608			Product Talstar Nursery Flowable Insecticide/Miticide			
Ingredient Bifenthrin: (2 methyl[1,1'-biphenyl]-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane carboxylate CAS# 82657-04-3						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	

		41134701			
72-6	Aquatic Organism Accumulation	40447601	FMC Corporation	OWN	
141-2	Toxicity of Residues on Foliage	40447601	FMC Corporation	OWN	
141-1	Acute Toxicity- Honeybee	00132538	FMC Corporation	OWN	

1 1 0	Name and Title Melinda Bowman	Date
Aulenda de Bruman	Product Registration Manager	August 8, 2013



#### U,S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

EPA 1. Number:	Date of Issuance:				
11556-155	MAR	14	201		
Term of Issuance:					
Unconditional					

NOTICE OF PESTICIDE:

X Registration Reregistration PNR1427 Insecticide

Name of Pesticide Product:

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Bayer HealthCare LLC Animal Health Division P.O. Box 390

Shawnee Mission, KS 66201-0390

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

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Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5). Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3).

1. Per 40 CFR 156.10(a)(6), submit one copy of your final printed labeling before releasing the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold". Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact BeWanda Alexander at www.alexander.bewanda@epa.gov or (703) 305-7460.

Signature of Approving Official: Gebken Product Manager Insecticide Branch/Registration Division (7505P)

March 14,2013

Enclosure

Reason To Issue: Revise according to EPA Notice of March 16, 2012

and propose other minor label corrections

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Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

#### PNR1427 Insecticide

Alternate Brand Names: Seresto Small Dog; Seresto Large Dog; Seresto Cat

#### Optional Language for Small Collar

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]]

[For 8-month prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older

-or-

[For 8-month prevention and treatment of ticks, fleas, and lice on (small) dogs and puppies 7 weeks of age and older and up to [(18 lbs.)(8 kg)] [body weight]] [and/or] prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older]

#### Optional Language for Large Collar:

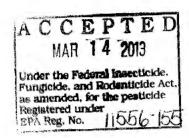
[For 8-month prevention and treatment of ticks, fleas and lice for 8 months on (large) dogs and puppies 7 weeks of age and older and above [(18 lbs.)(8 kg)] [body weight] ]

[Selected optional label claims bulleted here from pages 8 to 13]

ACTIVE INGREDIENTS:	
Flumethrin *	4.5%
Imidacloprid	
OTHER INGREDIENTS	
Total	100%

<sup>\*</sup>Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

Net Contents: (X) Collar	(s) - XX  oz.  (XX)	grams)	
EPA Reg. No. 11556-155	EPA Est.	No. 11556-TBI	)



Reason To Issue:

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#### Manufactured For

Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, Kansas 66201 USA

Made in Germany

#### READ THE ENTIRE LABEL BEFORE USE

[For small collar: USE ON [(DOGS)(CATS)]]

-or-

[For small collar: USE ON SMALL DOGS and CATS]

-or-

[For large collar: USE ONLY ON DOGS]

### DO NOT OPEN UNTIL READY TO USE DO NOT LET CHILDREN PLAY WITH THIS COLLAR [OR REFLECTORS]

### KEEP OUT OF REACH OF CHILDREN [CHOKING HAZARD - CONTAINS SMALL PARTS]

See [(back panel)(insert)] for Directions for Use.

#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS, call 1-800-422-9874.
- For medical emergencies involving ANIMALS, call 1-800-422-9874.

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#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

#### HOW TO APPLY

One collar per animal to be fastened around the neck.

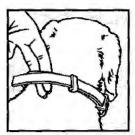
Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar. Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight (as a guide, it should be possible to insert 2 fingers between the collar and the neck). Pull excess collar through the loop(s) and cut off any excess length extending (1/one/an) inch (2 cm) beyond the loop(s).

[After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.]

#### [Optional Visuals:

#### Dog









- OF -

Reason To Issue: Revise according to EPA Notice of March 16, 2012

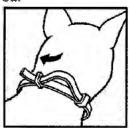
and propose other minor label corrections

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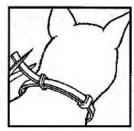
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Cat









The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when [(puppies)(kittens)] are rapidly growing.

This collar is designed with a safety-closure mechanism. In the unlikely event of a [(dog)(cat)(pet)] being trapped, the [(dog's)(cat's)(pet's)] own strength is sufficient to widen the collar to allow for quick release.

Replace the collar after 8 months for (optimal) (continuous) fleaand tick protection.

#### PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

[(PNR 1427 Insecticide)(Brandname)(This product)(The collar)] kills existing fleas on [(dogs)(cats)] within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in control of flea larvae in the [(dog's)(cat's)] surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) treated [(dog)(cat)].

Ticks already on the [(dog)(cat)] prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the [(dog)(cat)]. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

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Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours.

(Kills lice on dogs for a month.)
Aids in the treatment (and control) of Sarcoptic mange.

[(Seresto)(PNR 1427 Insecticide) (This product)(The collar)] is [(water resistant)(waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months.

Occasionally slight itching may be observed in animals that are not used to wearing collars in the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar (or reflectors,) or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. [Choking hazard. Contains small parts]. Do not place collar [or reflectors] in mouth. Not intended for use on humans.

For external use on [(dogs)(and)(cats)] only. Do not use on other animals. [(Do not use on puppies under seven weeks of age.)(Do not use on kittens under ten (10) weeks of age.)] Do not get this product in [(dog's)(cat's)] eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs of sensitivity occur remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your [(dog)(or)(cat)] is experiencing an adverse event, contact your veterinarian and, call I-800-422-9874.

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The patented Bayer polymer matrix system ensures that both active [(substances) (ingredients)] are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active [(substances)(ingredients)] are present in the [(cat's)(and/or)(dog's)] haircoat during the entire [(protection)(efficacy)] period. The active [(substances)(ingredients)] spread from the site of direct contact over the entire skin surface.

#### [INSERT DIAGRAM THAT DEPICTS RELEASE FROM MATRIX.]

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original unopened container in a cool, dry place that is

inaccessible to children.

Container Disposal: Dispose of container, pouch and expired collar in trash.

#### LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc. [The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.]

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#### Pouch Label

#### [(PNR 1427 Insecticide)(Brand name)]

4.5% flumethrin 10.0% imidacloprid

Do not let children play with this collar (or reflectors).
FOR USE ON (CATS)(DOGS)(CATS & DOGS)
See (outer container/leaflet/insert) for complete label information.
Do not open until ready to use.

BAYER HealthCare LLC, Animal Health Division

EPA Reg. No. 11556-155 EPA Est. No. 11556-TBD

Lot No. 0000000

and propose other minor label corrections

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Note to Reviewer: Brackets [ ] and parentheses ( ) denote optional language

#### Optional/Alternative Marketing Claims - Dogs

#### General Claims - Dogs

- Two active [(substances)(ingredients)] provide dual action against ticks, fleas, and lice (on dogs)
- For use on dogs and puppies 7 weeks of age and older
- Tick, (and) flea (and lice) (prevention)(control)(and) treatment for dogs 7 weeks of age or older
- [(PNR 1427)(Brand name)(This product)] is indicated for the prevention and treatment of ticks, fleas and lice on dogs and puppies (7 weeks of age and older)
- [Effective][Long-lasting] [protection] against ticks and fleas for 8 months
- Kills (and repels) ticks, (and) kills fleas (for 8 months)
- Reliable 8-month protection against ticks, and fleas on dogs (and puppies)
- [3-way] protection against fleas, ticks and lice
- 8-month protection against ticks and fleas
- For (small) dogs up to [(18 lbs.)(8 kg)] [body weight]
- For (large) dogs above [(18 lbs.)(8 kg)] [body weight]
- For external use on dogs
- For [(small dogs and puppies)(large dogs)]
- Fully effective within 48 hours after initial application of collar

#### **Tick Claims - Dogs**

- Repels and kills ticks for 8 months, including [(Deer)(Black-legged)] ticks, (Ixodes scapularis) (vector of Lyme disease and anaplasmosis), American dog ticks, (Dermacentor variabilis) (vector of Rocky Mountain spotted fever and ehrlichiosis), Brown dog ticks, (Rhipicephalus sanguineus) (vector of ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis, and Rocky Mountain spotted fever), and Lone Star ticks (Amblyomma americanum) (vector of ehrlichiosis) Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (Anaplasma phagocytophilium), Bartonellosis (Bartonella vinsonii, Bartonella spp.), Babesiosis (Babesia canis, B. gibsoni), Borreliosis (Borrelia burgdorferi), canine hemoplasmosis (Mycoplasma haemocanis), Ehrlichiosis (Ehrlichia canis, E. chaffeensis, E. ewingii), Hepatozoonosis (Hepatozoon canis and H. americanum), and Rickettsiosis (Rickettsia rickettsii) [,which are types of (canine) vector borne diseases]
- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (*Anaplasma phagocytophilium*), Bartonellosis (*Bartonella vinsonii, Bartonella spp.*),

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Babesiosis (Babesia canis, B. gibsoni), Borreliosis (Borrelia burgdorferi), canine hemoplasmosis (Mycoplasma haemocanis), Ehrlichiosis (Ehrlichia canis, E. chaffeensis, and E. ewingii), Hepatozoonosis (Hepatozoon canis and H. americanum), and Rickettsiosis (*Rickettsia rickettsii*) [,which are types of (canine) vector borne diseases]

- Kills [(Deer)(Black-legged)] ticks (, which may carry Lyme disease and Anaplasmosis)
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever and Ehrlichiosis)
- Kills all [(life)(blood feeding)] stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (intitial) application
- Prevents tick infestations within 48 hours after (inititial) application
- [(Kills)(Repels)] ticks in 6 hours after (intial) efficacy has been obtained
- Re-infesting ticks are [(repelled)(killed)(repelled and/or killed)] as quickly as 6 hours
- Protects against all types of ticks (attacking dogs)
- Protects your (dog)(and/or)(puppy) from all types of ticks (for 8 months)
- Easy, effective [(treatment and prevention)(control)] of ticks, (and) fleas (,and lice)

#### Flea Claims - Dogs

- (Rapidly/Quickly]) Kills fleas on dogs within [24] hours and continues to prevent infestations for 8 months
- Kills fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months
- Seresto aids in control of flea larvae in the dog's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide)]-treated dog.
- Aids in the control of flea larvae in the dog's immediate surroundings
- Protects your (dog)(and/or)(puppy) from fleas (for 8 months)
- For the treatment and prevention of flea infestations [on your dog (and in your dog's immediate surroundings)]
- One treatment prevents further flea infestations (on dogs) for 8 months
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents fleas on treated dogs from infesting (reinfesting) your home
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]
- For prevention and treatment of flea infestation(s) for 8 months

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- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on dogs
- Kills cat fleas (*Ctenocephalides felis*,) dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on dogs

\_\_\_\_\_

- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills fleas and may reduce the (risk/incidence) of tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii, Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Efficacy against fleas that may transmit tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii, Bartonella spp.*), and Rickettsiosis (*Rickettsia felis*) [,which are types of (canine) vector borne diseases]
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in dogs

#### Lice & Other Efficacy Claims - Dogs

- Kills [(biting) (chewing)] lice for a month
- For treatment and prevention of [(biting) (chewing)] lice (infestations)
- Controls existing [(biting) (chewing)] lice infestations
- Treats, prevents and controls [(biting) (chewing)] lice (infestations)
- Provides effective control of [(biting) (chewing)] lice (infestations)
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations of [(biting) (chewing)] lice
- Aids in the treatment (and control) of Sarcoptic mange

#### **Optional/Alternative Marketing Claims – Cats**

#### General Claims - Cats

- Two active [(substances)(ingredients)] provide dual action against ticks and fleas (on cats)
- For use on cats and kittens 10 weeks of age and older
- [Effective][Long-lasting] [ protection] for 8 months
- Tick, (and) flea (prevention)(control)(and) treatment for kittens 10 weeks of age or older
- Tick and flea treatment for cats and kittens 10 weeks of age and older
- [(PNR 1427)(Brand name) (The collar)(This product)] is indicated for the prevention and treatment of ticks and fleas on cats and kittens (10 weeks of age and older)
- Kills (and repels) ticks and kills fleas (for 8 months)
- (Reliable) (8-month) protection against ticks and fleas [on cats (and kittens)]
- [Dual] [2-way] protection against ticks and fleas

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For external use on cats

- For cats and kittens
- Fully effective within 48 hours after initial application of collar

#### **Tick Claims - Cats**

- Repels and kills ticks, including [(Deer)(Black-legged)] ticks, (Ixodes scapularis) (vector of Lyme disease and anaplasmosis), American dog ticks (*Dermacentor* variabilis) (vector of Rocky Mountain spotted fever, cytauxzoonosis, and ehrlichiosis), Brown dog ticks, (Rhipicephalus sanguineus) (vector of ehrlichiosis, anaplasmosis, babesiosis, and Rocky Mountain spotted fever), and Lone Star ticks (Amblyomma americanum) (vector of cytauxzoonosis and ehrlichiosis) (for 8 months)
- Treatment with [(PNR 1427)(brand name)(this product)(the collar)] kills ticks that may vector Anaplasmosis (Anaplasma phagocytophilium), Babesiosis (Babesia canis, B.spp.), Borreliosis (Borrelia burgdorferi), Ehrlichiosis (Ehrlichia canis, E. spp.), Cytauxzoonosis (Cytauxzoon felis), and Rickettsiosis (Rickettsia rickettsii) [, which are types of (cat) vector borne diseases]
- Efficacy against ticks (by repelling and killing) that may vector Anaplasmosis (Anaplasma phagocytophilium), Babesiosis (Babesia canis, B. spp.), Borreliosis (Borrelia burgdorferi), Ehrlichiosis (Ehrlichia canis, E. spp.), Cytauxzoonosis (Cytauxzoon felis), and Rickettsiosis (Rickettsia rickettsii) [, which are types of (cat) vector borne diseases]
- Kills [(Deer)(Black-legged)] ticks (, which may vector Lyme disease)
- Kills American dog ticks (, which may vector Rocky Mountain spotted fever)
- Kills all (life) (blood feeding) stages of ticks
- Kills tick adults, larvae, and nymphs
- Kills ticks within 48 hours of (intitial) application
- Prevents tick infestations within 48 hours after (initial) application
- Protects against all types of ticks (attacking cats)
- Protects your (cat)(and/or)(kitten) from all types of ticks (for 8 months)
- Easy, effective [(treatment and prevention)(control)] of ticks and fleas

#### Flea Claims - Cats

- (Rapidly/Quickly) Kills fleas on cats within [24] hours and continues to prevent infestations (for 8 months)
- Kills and repels fleas before they lay eggs
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation (lasting 8 months)

Reason To Issue:

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- Seresto aids in control of flea larvae in the cat's surroundings following contact with a [(Seresto)(PNR 1427 Insecticide) (brand name)]-treated cat.
- Aids in the control of flea larvae in the cat's immediate surroundings
- Protects your (cat)(and/or)(kitten) from fleas (for 8 months)
- For the treatment and prevention of flea infestations on your cat (and in your cat's immediate surroundings)
- One treatment prevents further flea infestations (for 8 months)
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Treatment with [(PNR 1427)(brand name)(the collar)(this product)] kills fleas and may reduce the incidence of [flea allergy dermatitis (FAD)][flea bite hypersensitivity (FBH)][flea bite dermatitis (FBD)]
- For prevention and treatment of flea infestation(s) for 8 months
- [8-month] prevention and treatment of cat fleas (*Ctenocephalides felis*), dog fleas (*Ctenocephalides canis*) and human fleas (*Pulex irritans*) on cats
- Treatment with [(PNR 1427)(brand name) (the collar)(this product)] kills fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Efficacy against fleas that may vector Bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), Feline infectious anemia (*Mycoplasma spp.*), and Rickettsiosis (*Rickettsia felis*)
- Stops fleas from feeding by (their) paralysis and death
- Kills fleas that may cause anemia in cats

#### Other Efficacy Claims - Cats

• Aids in the treatment (and control) of Sarcoptic mange

#### Optional/Alternative Marketing Claims – General

- Protects against ticks and fleas for 8 months
- (8-month) [(protector band)(pet collar)(collar)]
- [(Kills)(Protects)] against ticks and fleas for 8 months
- (Make sure to) replace (the) collar after 8 months [for year-round tick and flea (control)(prevention)]
- Remains effective after bathing or swimming
- Remains effective following shampooing, swimming or after rain
- [(Wetness)(Moisture)] does not reduce the collar's effectiveness
- No need to remove (the) collar while bathing pet
- No need to remove collar when (your) pet goes swimming or [(gets bathed)(bathing)]

Date: 02/14/13 Supersedes: 03/12/12 Page 13 of 13

• [(Seresto)(PNR 1427 Insecticide) (Brand name) (This product)(The collar)] is [(water resistant)(waterproof)] and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months.

- Fragrance-free
- Odorless
- No (noticeable) odor
- Non-greasy
- Easy to use
- (Easy)(convenient)(to use)(to apply)
- [(Graphite)(Gray)][Red][Yellow][(collar)(color)]
- (Adjustable)(convenient)(easy-to-apply) collar
- (Light) reflectors for added visibility (in the evening and at night)
- (Three) (3) (visibility) reflectors (included)
- (Snap-on) reflectors (included) for added (night-time)(pet)(visibility)
- One collar per animal (to be fastened around the neck)
- Contains one collar
- [(Patented)(Bayer)(technology) (polymer)(matrix)(system)] ensures that both active [(substances)(ingredients)] are (slowly) (and continuously) released (in low concentrations).
- (Patented) (Bayer) (Polymer) Matrix: [(effective)(dependable)(long-lasting)] (flea and tick) control (for 8 months)
- (Depot effect:) [Active (substances)(ingredients)] stored inside the polymer matrix and gradually released over time]
- [(Continuous)(Even distribution)(Steady)] release) of active [(substances)(ingredients)] (over 8 months)
- (Continuous) flea and tick protection (over 8 months)
- Contains [(Patented)(Bayer) (polymer)(matrix)(system)]

### Optional/Alternative Marketing Claims – Combined label for small collar for use on small dogs and cats

For external use on small dogs and cats only



### Baver HealthCare Animal Health

Via Federal Express

February 14, 2013

Document Processing Desk (AMEND - NO REGFEE) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attention:

Mr. Richard Gebken/PM10

Registration Division (7505P)

Subject: Flumethrin Technical (EPA Reg. No. 11556-154)

PNR1427 Insecticide (EPA Reg. No. 11556-155); ABN: Seresto Amendments to remove time-limited registration designations

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201 0390



Dear Mr. Gebken:

Reference is made to the Notices of Pesticide Registration for the subject products, both dated March 16, 2012. These registrations were given oneyear time-limited registrations which will expire on March 17, 2013. Since Bayer HealthCare LLC, Animal Health Division, has complied with the conditions of these registrations, we ask that the time limitations for these registrations be removed.

As requested, please find enclosed Pesticide Applications and draft labeling, text dated 02/14/2013, for the subject products (3 copies each) that have been revised pursuant to the guidance given in the respective Notices of Registration, dated 3/16/2012. Due to the nature of some of the requested revisions to the PNR1427 Insecticide label, we have enclosed a red-lined version of this draft label showing the revisions and deletions, in hopes this will allow the Agency to do a more expeditious review of the label.



Therefore with the submission and review of the enclosed labels, we ask the Agency to remove time-limited registration designations for the subject products before the March 17, 2013 expiration date.



If you have any questions, please do not hesitate to call me at 913-268-2751.

Sincerely,

Douglas A. Spilker. Ph. D.

Manager, EPA Regulatory Affairs

Doug Spilker@Bayer.com

#### Enclosures:

- 1. Application for Pesticide Amendment, dated 2/14/2012, for Flumethrin Technical
- 2. Draft Labeling, text dated, 2/14/2013 for Flumethrin Technical (3 copies)
- Application for Pesticide Amendment, dated 2/14/2012, for PNR1427 Insecticide, with attachments
- Draft Labeling, text dated, 2/14/2013 for PNR1427 Insecticide (3 copies)
- Draft Labeling, text dated, 2/14/2013 for PNR1427 Insecticide (1 copy) – with red-lining

Cc: Ms. B. Alexander (cover letter only via email)





### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

February 20, 2013

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DR. BRUCE MARTIN
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: PNR1427 INSECTICIDE

COMPANY NAME: BAYER HEALTHCARE LLC

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 11556-155 EPA RECEIPT DATE: 02/19/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

Please read instructions on reve	rse before completing fo	rm.		·		Form Approved, OMB No. 2070-0060	
O EDA	Unite	d States		☐ Registr	ation	OPP Identifier Number	
<b>₩</b> EPA	Environmental I	Protection A	gency	⊠ Amend			
	Washington, DC 2046			☐ Other:			
	A	pplication 1	for Pesti	ide - Section			
1. Company/Product Number			2. EPA Prod	uct Manager	<del></del>	3. Proposed Classification	
11556-155			Richard G	ebken			
4. Company/Product (Name) PNR1427 Insecticide		ı	PM# 10			None Restricted	
5. Name and Address of App		, ,		ed Review. In	accordance	with FIFRA Section 3(c)(3)	
Bayer HealthCare LL	C, Animal Health	t '	(b)(I), my product is similar or identical in composition and labeling				
PO Box 390 Shawnee Mission, KS	66201		to: EPA Reg. No.				
Check if this is a		-	Product Name				
ONOGK II BIID IS	The dances		Section -				
Amendment – Explain t	pelow.		-	Final printed lab	els in response	to Agency letter dated	
	nse to Agency letter date	ed	_ [	] "Me Too" Applica	•		
Notification - Explain be				Other - Explain t			
Explanation: Use add							
Non-PRIA Action: Refe							
						rch 17, 2013. Since Bayer	
HealthCare LLC, Anima		•			-		
limitation for this registr		rease ring att	acned add	itionai intorma	non menuam	g draft labeling, dated	
2/14/2013, for the subject	a product.					i	
			Section -	III			
1. Material This Product Wil	Be Packaged In:			C-C-5-111-5-1			
Child-Resistant Packaging Yes*	Unit Packag  Yes	ing	"	Vater Soluble Pack Yes	aging	Type of Container     Metal	
No No	│ ☐ No		No Yes			Plastic	
	If "Yes"	No.	P	"Yes"	No. per	Glass	
*Certification must	Unit Packag	ing wgt. cont	tainer F	Package wgt.	container	Paper	
be submitted						Other (Specifiy)	
3. Location of Net Contents	Information	4. Size(s) Retail	Container			of Label Directions	
Label	Container				On Lab		
6. Manner in Which Label is	6. Manner in Which Label is Affixed to Product Lithograph Other				ling accompanying product		
☐ Paper glued ☐ Stenciled							
Section - IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)							
Name		Title	) <i>(</i>	DA Damilata	A CC. :	Telephone No. (include Area Code)	
Douglas A. Spilker, Ph.D.  (doug.spilker@bayer.com)  Manager, EPA Regulatory Affairs				913-268-2751			
Certification 6. Date Application							
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.							
			itle Manager,	EPA Regulatory	Affairs		
Typed Name		5. Da	te	¬ _ =	, O	- I	
Douglas A. Spilker, Ph.D.			4 H	6 20	/ イ		

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

# ATTACHMENT FOR APPLICATION FOR PESTICIDE REGISTRATION February 14, 2013

#### PNR1427 Insecticide (EPA Reg. No. 11556-155)

Reference is made to the Notice of Pesticide Registration for the subject product, dated 3/16/2012. This registration was given a one-year time-limited registration which will expire on 3/17/2013. Since Bayer HealthCare LLC, Animal Health Division, has complied with the conditions of this registration, we ask that the time limitation for this registration be removed.

As requested, please find enclosed revised draft labeling, text dated 02/14/2013, for the subject product (3 copies) that has been revised pursuant to the guidance given in the respective Notice of Registration, dated 3/16/2012, and to make a few other minor label revisions. Due to the nature of some of the requested revisions to the PNR1427 Insecticide label, we have enclosed a red-lined version of this draft label showing the revisions and deletions, in hopes this will allow the Agency to do a more expeditious review of the label. A brief listing of the respective changes is listed below, and includes:

Draft Label Page No.	Changes made
1	<ul> <li>Deletion of full chemical name, see acceptance of this in email from Kerry Leifer, dated 4/18/12 (attached)</li> <li>Addition of EPA Reg. No.</li> </ul>
2 & 3	Removal of unnecessary and redundant words
4	<ul> <li>Correction of statements regarding lice and flea larvae per EPA's Notice of Pesticide Registration (NPR), dated 3/16/12</li> </ul>
5	<ul> <li>Correction of statement per NPR, dated 3/16/13</li> <li>Relocation of the "loss of collar" statement to a more appropriate spot on the label</li> </ul>
6	<ul> <li>Replacement of the word "leaflet" with "insert"; Marketing request.</li> </ul>
7	<ul> <li>Rearrangement of ingredients</li> <li>Addition of the word "insert" as option.</li> <li>Addition of EPA Reg. No.</li> </ul>
8 – 13 (8 -14 of Highlighted version)	Revisions per NPR, dated 3/16/2012

Therefore with the submission and review of the enclosed labels, we ask the Agency to remove the time-limited registration designations for the subject products before the March 17, 2013 expiration date. If there are any questions regarding these revisions, please contact us immediately [doug.spilker@bayer.com; (913)-268-2751].

#### Via Federal Express

Attn: Richard Gebken (PM 10)

Document Processing Desk (Final Printed Labeling)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

#### **Enclosure:**

Application for Pesticide (Other) – PNR 1427 Insecticide (EPA Reg. No. 11556-155)

Submission of Final Printed labeling for Alternate Brand Names:

Seresto Small Dog Seresto Large Dog Seresto Cat

Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390

Seresto FPL 11-28-12 Submission Cover.doc

## Fee for Service

### {931190Å~

This package includes the following	for Division				
○ New Registration	ORDD				
<ul><li>Amendment</li></ul>	○ BPPD ○ RD				
□ Studies? □ Fee Waiver?	Risk Mgr. 10				
□ volpay % Reduction:	Trior mgr				
Receipt No. S-	931190				
EPA File Symbol/Reg. No.	11556-155				
Pin-Punch Date:	2/19/2013				
This item is NOT subject to FFS action.					
Action Code:	Parent/Child Decisions:				
Requested:					
Granted:					
Amount Due: \$					
Inert Cleared for Intended Use	Uncleared Inert in Product				
Reviewer: H. GARVIC	Date: <u> </u>				
Remarks:					